OcuScan® RxP
Measuring System

OPERATOR'S MANUAL

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OcuScan® RxP Operator's Manual
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MANUAL REVISION RECORD

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Dec. 2003	B	ECN 20033945 - Updated information for the Patient Viewer template along with other miscellaneous changes. Changed pages include: i(title) - iii, vi, 1.2, 1.4, 1.8, 2.4, 3.1, 3.2, 3.38, 3.39, 3.42 - 3.48, 4.1, 5.2. 6.1.
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PREFACE

This manual is your guide to the *OcuScan*® RxP Measuring System, and considers all options available to the user; therefore, when reading this manual you only need to pay attention to those options which apply to your specific unit. Please read the entire manual carefully before operating the instrument.

Warnings, cautions, and notes contained in this manual are important and must be followed. A WARNING! statement is written to protect individuals from bodily injury. A caution statement, with the CAUTION heading centered above the text, is written to protect the instrument from damage.

If you have questions, or want additional information, please contact your local Alcon representative or the Alcon Technical Services Department at:

Alcon Laboratories, Inc.
15800 Alton Parkway
Irvine, California 92618-3818
(949) 753-1393
FAX (949) 753-6614

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

SECTION ONE
GENERAL INFORMATION

The *OcuScan*® RxP Measuring System

The *OcuScan*® RxP Measuring System is an ophthalmic ultrasound system designed to enhance patient care by providing high quality eye measurements in an easy to use format. The system is used for A-scan Biometry and Pachymetry applications.

Biometry consists of measuring the axial length of the eye. By applying axial length (AL) and keratometry (K) readings into various IOL calculation formulas, the system calculates the power of the intraocular lens to be implanted in the patient's eye.

Figure 1-1 OcuScan® RxP Measuring System

Pachymetry consists of measuring corneal thickness at one or several points on the cornea. It is often performed during a Biometry examination and prior to refractive surgery such as Lasik or PRK. Corneal thickness measurements may aid in determining the risk of developing Glaucoma and the evaluation of intraocular pressure (IOP).

Please take a few minutes to familiarize yourself with the *OcuScan*® RxP Measuring System by scanning patients with previously known diagnoses and measurements. Experiment with various clinical situations until you feel comfortable with your new system. Various enhancements have been made in both Contact and Immersion modes, therefore if you are using customized constants derived on a system other than the *OcuScan*® RxP Measuring System, it is recommended to derive new customized constants using the *OcuScan*® RxP Measuring System.

This operator's manual is designed to provide the necessary information for setting up and learning to operate the system, and to provide a reference source for the various menus and selections.

The most effective use of diagnostic ultrasound requires a complete understanding of the functional aspects of the instrument and the clinical significance of ultrasound traces. Users of ultrasonic equipment should study professional literature and obtain approved medical training in the interpretation of ultrasound traces and in obtaining accurate measurements of the eye's axial length and corneal thickness. Professional literature should also be used to decide on the appropriate IOL power calculation formula for a particular patient.

QUICK START

1. INSTALL THE SYSTEM

1.1 Perform the installation instructions on the next page.

NOTE: For detailed setup information, refer to Section Three: Operating Instructions.

2. SYSTEM SETUP

2.1 From the Menu screen, tap (or press) **System Setup**.

2.2 Input the **Clinic** and **Operator** names. Tapping on a field will display a keyboard that allows you to input the textual information. There are five operator's selections that can be named as desired.

2.3 Set the action of the Print/Save button using the **Records** selection. Tapping the button advances through the four selections as follows: Current Screen, Full Report, Full Report and Save, and Display Menu.

2.4 Enter the **Date** and **Time**.

2.5 Select a **Language**.

2.6 Select the **Video Mode**: LCD only or SVGA mode to connect an external monitor.

2.7 Select a **Save Patient Format**. Use PC Format if you plan to export patient data to a Personal Computer, otherwise use Compact Flash format to conserve space on the optional Compact Flash card.

2.8 Tap **OK** to return to the Menu screen. When prompted, tap the checkmark button to save the changes.

3. SETTING UP THE BIOMETRY PRESETS

3.1 From the Menu screen, tap the Biometry button.

3.2 Tap in the **Settings** frame to enter the Biometry Presets screen.

3.3 Enter a name for each of the five available **Presets** as desired. Change to a different preset by tapping on the Preset drop down menu then tap on a different Preset number.

3.4 Change the default **Settings** as necessary.

3.5 Select the screens in the **Secquence** box that will be displayed during the procedure. The Sequence determines which screen will be displayed next when tapping the Next arrow button. When the end of the sequence is reached, the system loops back to the beginning.

3.6 If necessary, edit the **Pseudo** or **Phakic IOL Defaults** to your desired values. First select a Material then tap the Edit button. Enter the desired changes in the IOL Edit box.

3.7 Enter your preferred lenses in the Lens Constant screen.

3.8 Tap **OK** to return to the Biometry Scan screen. When prompted, tap the checkmark button to save the changes.

4. ENTERING PATIENT DATA

4.1 Tap the **Patient** frame.

4.2 Tap the New Patient button.

4.3 Enter a Patient Name and ID. A patient ID is required to save patient data.

4.4 Select the desired **Preset** and **Operator**. These were setup in the previous steps.

4.5 Enter the patient data for each eye.

4.6 Tap the arrow button to return to the Biometry Scan

5. *The OcuScan® RxP Measurement System is now ready to perform biometry examinations and calculate the IOL power.*

NOTE: Be sure to save the data after the exam. The Save button is available on the Patient Information screen or by pressing the Print/Save button if it is programmed to Display Menu.

INSTALLATION INSTRUCTIONS

The *OcuScan*® RxP Measuring System is shipped in damage resistant cardboard crates. The components must be removed from the crates, set on a secure work surface, and assembled as described below. Be sure to make cable connections exactly as instructed.

NOTE: Four threaded holes are provided on the bottom side of the console to attach the system to a cart or table if desired. Refer to Figure 1-2 for layout and dimensions of the hole pattern.

1 From the external power supply unit, plug the 24 VDC power input cable connector into the *OcuScan*® RxP rear panel (see Figure 2-2).

2 From the external power supply unit, plug the power cord into a 110-120 VAC or 200-240 VAC power source. The power supply is self-adjusting and will adapt automatically to either power source. **NOTE: The power cord used to connect the power supply to the wall outlet is shipped with systems for use in the U.S.A. and Canada only. For other countries, a power cord with appropriate ratings and national safety agency approval must be used.**

3 Set the footswitch on the floor and plug its cable connector into the footswitch mini din connector on the *OcuScan*® RxP rear panel .

4 Plug the biometry probe cable into the BIOMETRY connector on the rear panel, then place the probe in the probe holder on the right side of the console with the probe tip pointing upwards. Plug the pachymetry probe cable into the PACHYMETRY connector, then place the probe in the probe holder on the left side of the console with the probe tip pointing upwards.

5 Verify that a paper roll is installed in the printer compartment on the front of the console. If not, install a new paper roll as detailed in Section Four: Care and Maintenance.

6 If a Patient Records Compact Flash card has been purchased with the system, insert it into the slot on the left side of the console with the insert arrow facing up and pointing towards the slot (see Figure 1-3).

7 Place the stylus into the holder on top of the console (see Figure 2-1).

8 *If you have power supply model PMP130-14-S*, turn the system ON by pressing the switch on the external power supply to the ON position.

If you have power supply model PCM 80PS24, the power will turn on when the power cord is plugged into the wall outlet. The LED on this model indicates that the power is on.

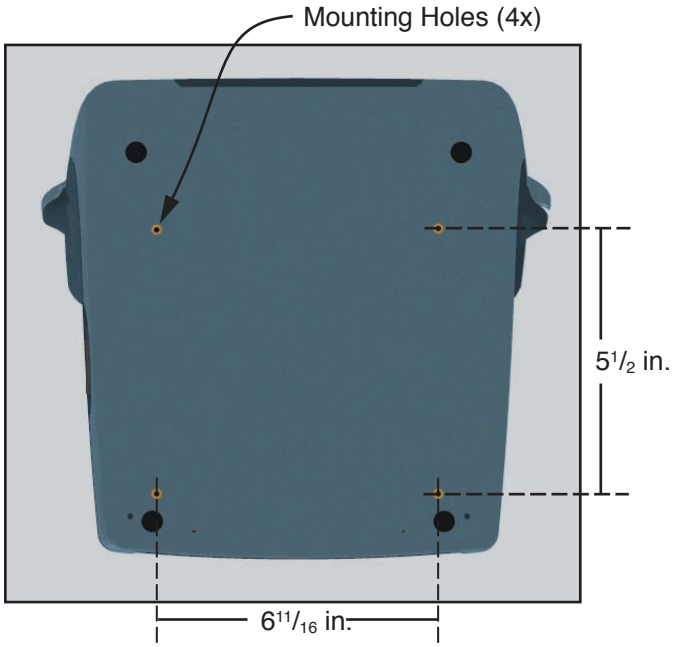

Figure 1-2 MOUNTING HOLES - The system can be mounted to a cart or table using the threaded mounting holes shown in this illustration. Use screws with a M5 x 0.8 thread and the appropriate length to extend through the surface of the table or cart.

INSTALLING OPTIONAL SOFTWARE AND UPGRADING SYSTEM SOFTWARE

Optional software is available for the *OcuScan*® RxP Measuring System and can be ordered by following the directions in Section Six: Accessories and Parts. The optional software and system software upgrades are delivered on a Compact Flash card and are installed as follows:

1 Insert Compact Flash card containing new software into the slot on the side of the system as shown in Figure 1-3.

2 For systems with REF number 685-0000-501 (see label behind display panel), turn the system power OFF then back ON.

For systems with REF number 685-0000-502 and above, reset the system by pressing and holding the standby switch for 7 seconds. The software is automatically installed. When upgrading the system software, a status bar is displayed showing the progress of the upgrade installation.

NOTE: The Compact Flash card containing the optional software will only work for one upgrade and the same card can be used for storing patient data thereafter. It is recommended to re-label the card if using it for patient data.

Figure 1-3 INSERTING THE COMPACT FLASH CARD - Insert the Compact Flash card as shown in this figure.

NOTES, CAUTIONS, AND WARNINGS

NOTES:

- **All data that has been entered or displayed on any screen must be verified by the operator for correctness and completeness before progressing from one screen to another.**
- **It is recommended to perform a probe check prior to starting a biometry session. A probe check should also be done when a new probe is used.**
- **On systems 685-0000-502 and above (see REF number on label), pressing and holding the standby switch for 7 seconds then releasing will reset (reboot) the system.**

CAUTIONS

- **This device is intended for healthcare professionals who are trained in A-scans, IOL power calculations, and/or pachymetry measurements.**
- **Do not clean console and accessories with solvents or abrasives; irreparable damage will result.**
- **Biometry and Pachymetry probes are fragile components which must not undergo rough use or handling; this can destroy or alter operation of the probe.**
- **Avoid touching touch screen with gel or sterile prism solution.**
- **To ensure compliance with IEC 601-1-1 (requirements for medical electrical systems), do not use power strips (portable multiple socket outlets) to power the *OcuScan*® RxP system.**
- **Using the system with a hospital grade power cord and proper hospital grade grounded electrical outlet assures electrical safety.**
- **In accordance with ALARA principles, the energy delivered to the eye should be as low as is reasonably achievable.**
- **If the identification of the IOL or its constants is changed, be sure to update the A Constant, S-Factor, and ACD.**
- **Consult the IOL manufacturer if you have questions regarding IOL constants.**
- **It is very important to verify that the correct default velocities and thicknesses are displayed prior to measuring Axial lengths and corneal thickness.**
- **Prior to initiating the COMPUTE function in the LENS CONSTANT UPDATE screen, verify the data entered is correct.**

WARNINGS!

- **The Alcon Laboratories ultrasound probes and equipment are NOT designed or intended for fetal use.**
- **Not suitable for use in the presence of flammable anesthetic, oxygen, or nitrous oxide.**
- **Do not use this product on eyes when corneal integrity is compromised by infection or trauma.**
- **Do not use the system if it displays error messages or acts erratically.**

EMC Statement

It is important to install and use the equipment in accordance with the instructions in order to prevent harmful interference with other devices in the vicinity. If this equipment causes harmful interference to other devices (determined by turning the equipment off and on), the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the other device(s).
- Increase the distance between the equipment.
- Connect this equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer or your Alcon field service engineer for help.

CAUTION

The *OcuScan*® RxP Measuring System needs to be installed and put into service according to the EMC information provided in Tables 1-1 through 1-3. Portable and mobile RF communications equipment can affect this medical electrical equipment.

Use of accessories and cables other than those provided may result in increased emissions or decreased immunity of the system.

The *OcuScan*® RxP Measuring System is intended for use in the electromagnetic environment specified in Tables 1-1 and 1-2. The customer or the user of the *OcuScan*® RxP Measuring System should assure that it is used in such an environment.

Table 1-1
Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The *OcuScan®* RxP Measuring System uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *OcuScan®* RxP Measuring System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 1-2
Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	• +6 kV contact • +8 kV air	• +6 kV contact • +8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	• +2 kV for power supply lines • +1 kV for input/ output lines	• +2 kV for power supply lines • +1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 601-4-5	• +1 kV differential mode • +2 kV common mode	• +1 kV differential mode • +2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	• <5% U_T (>95% dip in U_T for 0.5 cycle) • 40% U_T (60% dip in U_T for 5 cycles) • 70% (30% dip in U_T for 25 cycles) • <5% (>95% dip in U_T for 5 sec)	• <5% U_T (>95% dip in U_T for 0.5 cycle) • 40% U_T (60% dip in U_T for 5 cycles) • 70% (30% dip in U_T for 25 cycles) • <5% (>95% dip in U_T for 5 sec)	Mains power quality should be that of a typical commercial or hospital environment. If the uses of the *OcuScan®* RxP Measuring System requires continued operation during power mains interruptions, it is recommended that the *OcuScan®* RxP Measuring System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 601000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level.

Table 1-2 continued on the next page...

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Table 1-2
Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the *OcuScan®* RxP Measuring System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency to the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating to the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 6100-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the (equipment or system) is used exceeds the applicable RF compliance level above, the (equipment or system) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *OcuScan®* RxP Measuring System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The *OcuScan*® RxP Measuring System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *OcuScan*® RxP Measuring System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *OcuScan*® RxP Measuring System as recommended in Table 1-3, according to the maximum output power of the communications equipment.

Table 1-3
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the *OcuScan*® RxP Measuring System

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Note 1: For transmitter rates at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 2: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Universal Precautions

Universal precautions shall be observed by all people who come in contact with the instrument and/or accessories to help prevent their exposure to blood-borne pathogens and/or other potentially infectious materials. In any circumstance, wherein the exact status of blood or body fluids/tissues encountered are unknown, it shall be uniformly considered potentially infectious and handled in accordance with OSHA guidelines.

Underwriter's Laboratories

The *OcuScan*® RxP Measuring System is classified by Underwriter's Laboratories, Inc., with respect to Electric Shock, Fire, Mechanical, and other specified hazards only in accordance with UL 2601-1 and CAN/CSA C22.2 No. 601.1.

Accessory Equipment

Accessory equipment connected to or used with this equipment must be certified according to the respective IEC standard (e.g. IEC 950 for data processing equipment and IEC 601-1-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 601-1-1. Anyone connecting additional equipment, or otherwise causes a different system configuration than provided by Alcon, is responsible for continued compliance to the requirements of the system standard IEC 601-1-1. If in doubt, consult Alcon Technical Services at 949/753-1393 or contact your local Alcon representative.

Environmental Issues

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components and packaging.

User Information – Environmental Considerations

The equipment that you have purchased requires the use of natural resources for its production. This equipment may also contain hazardous substances which could have potential effect on the environment and human health if disposed of improperly.

In order to avoid the entry of any such substances into our environment and to promote natural resource conservation, we encourage you to use the appropriate take-back systems. Such take-back systems reuse or recycle many of the materials in your end-of-life equipment in a beneficial way. Please contact your local Alcon office for assistance in take-back options through Alcon or other providers.

The crossed-bin symbol located on this equipment reminds you to use take-back systems, while also emphasizing the requirement to collect waste equipment separately, and not dispose of it as unsorted municipal waste.

If you need more information on the collection, reuse or recycle systems available to you, please contact your local or regional waste administration, or contact your local Alcon office for more information.

Safety Requirements

The *OcuScan*® RxP Measuring System complies with the following safety agency standards for medical instruments: IEC 601-1, IEC 601-1-1, IEC 601-1-2, IEC 601-1-4, UL 2601. The system meets all essential requirements of Medical Device Directives 93/42/EEC.

The system complies with FDA acoustic power measurement limits, IEC 60601-2-37 and meets the Acoustic Output Declaration Exemption for IEC 1157.

1 - Acoustic Output Measurements -
Statistical analysis of Ultrasound Power Measurements per FDA 510(k) Diagnostic Ultrasound Guidance.

Probe	I_{spta} X	MI X
10 MHz Biometry	0.12	0.21
20 MHz Pachymetry probe	0.51	0.13

I_{spta} X is the derated spatial-peak temporal-average intensity in mW/cm^2 (milliwatts per square centimeter). MI is the Mechanical Index. X stands for upper output parameter statistical limits.

2 - IEC 1157 – Acoustic Output Declaration Exemption

The *OcuScan*® RxP Measuring System meets the three exemption conditions specified by IEC 1157 as follows:

- The peak-negative acoustic pressure does not exceed 1 MPa.
- The output beam intensity does not exceed 20 mW/cm^2.
- The spatial-peak temporal-average intensity does not exceed 100 mW/cm^2.

The averages of the measurements conducted per IEC 1157 of several samples of the 10 MHz Biometry and 20 MHz Pachymetry probes were as follows:

Probe	Biometry (10MHz)	Pachymetry (20MHz)
Peak negative acoustic pressure (MPa)	0.69	0.54
Output beam intensity (mW/cm^2)	0.03	0.09
Spatial-peak temporal-average intensity (mW/cm^2)	0.15	0.57

PRODUCT SERVICE

For product service, please contact Alcon's Technical Services Department at the number provided below.

Operators experiencing problems with the system should refer to the Operating Instructions and Troubleshooting sections of this manual. A problem which persists should be referred to the Alcon Technical Services Department or your local authorized service representative.

For optimum performance, it is the user's responsibility to schedule preventive maintenance service on the system and its accessories one time each year. Alcon's Field Service Engineers are trained and equipped to provide the highest quality of workmanship.

Safety performance should be verified by the user (e.g., qualified service personnel) at least twice a year. Ground resistance, leakage current and dielectric withstand voltage must be checked to appropriate national standard.

To avoid unnecessary shipping, please contact your Alcon Technical Services Department prior to return of any system or accessories. If return of the equipment is deemed necessary, a Return Material Authorization will be issued with appropriate shipping instructions.

Alcon Laboratories, Inc.
Technical Services Department
15800 Alton Parkway
Irvine, California 92618-3818
(949) 753-1393 or (800) 832-7827

LIMITED WARRANTY

Alcon will repair or replace at its option, any system or accompanying accessories found to be defective in material and/or workmanship for a period of one (1) year from the date of initial installation. This warranty applies to the original purchaser of the system, when said system is properly installed, maintained, and operated in accordance with published instructions.

Alcon shall not be obligated to provide services under this warranty for damage to or destruction of systems covered where such damage or destruction is a result of or caused by fire or explosion of any origin, riot, civil commotion, aircraft, war, or any Act of God including, but not limited to lightning, windstorm, hail, flood or an earthquake.

This warranty does not cover damage resulting from service repair or other alteration by any person other than an Alcon-authorized service person, and any warranties provided by Alcon with respect to this equipment shall become void and of no further force and effect if this equipment is serviced by anyone other than Alcon-authorized service personnel. In particular, Alcon shall have no obligation to replace, repair or credit customer’s account for the cost of the equipment, which has been subject to service or other alteration by persons other than Alcon-authorized service personnel.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF ALCON, AND THE REMEDY PROVIDED ABOVE IS IN LIEU OF ANY AND ALL OTHER REMEDIES. THERE ARE NO OTHER AGREEMENTS, GUARANTEES, OR WARRANTIES – ORAL OR WRITTEN, EXPRESS OR IMPLIED – INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ALCON SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF ANY DEFECT, IMPROPER USE, OR UNAUTHORIZED SERVICE OR REPAIR.

Table 1-4
OCUSCAN® RxP SYSTEM SPECIFICATIONS

CONSOLE DIMENSIONS

Height:	30.5 cm (12.0 inches)
Width:	30.5 cm (12.0 inches)
Depth:	27.9 cm (11.0 inches)

WEIGHT	Packed	Unpacked
Console & Accessories	6.62 kg (14.60 lbs)	4.85 kg (10.70 lbs)

ENVIRONMENTAL REQUIREMENTS

	Operating	Storage
Temperature:	10° C to 35° C 50° F to 95° F	-10° C to 55° C -18° F to 131° F
Altitude:	-125 m to +2500 m	-125 m to +6100 m
Humidity:	30% to 75%	10% to 95%
Noise Level:	Sound pressure level does not exceed 44 dbA measured at one meter.	

ELECTRICAL CHARACTERISTICS

The instrument automatically sets itself to operate with the supplied voltage and frequency.

Input AC Voltage/Current: to power supply	100-120 V~/200-240 V~, 2A
Frequency:	50/60 Hz
Input DC Voltage/Current: to console	24 VDC ±2V with minimum of 3.3 A from an external power module.
Insulation Class:	Class I, type BF  Continuous operation.

SYSTEM PERFORMANCE

Internal Video Display:	SVGA 800 x 600
External Video:	SVGA

Biometry

Probe frequency:	10 MHz ±1 MHz
Theoretical Accuracy:	±0.05 mm
Clinical Accuracy:	±0.1 mm
Axial Length Range:	15 - 39 mm
Gain Range:	Adjustable from 40 to 80 dB
Memory:	Biometry Measurements: 10 per eye Physician Settings: 5 IOL Slots per Setting: 10 (editable)
Display:	AL (10), average AL, Standard Deviation, Lens thickness, ACD, and Vitreous
IOL Formulas:	Holladay®, SRK II, SRK T, Binkhorst II, Hoffer Q, Haigis (optional)

Pachymetry

Probe frequency:	20 MHz ±2 MHz
Resolution:	±1 μm
Accuracy:	±5 μm
Measurement Range:	100-350, 400-700, and 300-1100 μm
Bias:	
Actual:	Actual measurement
Percentage:	0 to 300%
Absolute:	-999 to 999 μm
Gain:	Auto adjusting
Memory:	
Single Point:	10 programmable points
Map 1 or 2:	25 programmable points
LASIK:	3 points in each of four phases
Physician settings:	5
Display:	
Single Point:	Min, Avg, SD, Adjusted IOP
Map 1 or 2:	Last, Average, and Minimum readings
LASIK:	Minimum reading, Flap achieved, Potential Ablation, Ablated, Potential Enhancement

TYPE BF EQUIPMENT, providing both the attributes of basic insulation and "floated" isolation.

Dangerous Voltage
Used for U.S. Approval to Indicate:
Caution: To reduce the risk of electric shock, do not remove cover (or back). Refer servicing to qualified service personnel.

Attention, consult ACCOMPANYING DOCUMENTS

Alternating current

Direct current

Footswitch connection

SVGA color video

Protective ground

Equipotential ground connection

Ethernet Connection

USB Connection

101010

RS232 Serial Connection

Use appropriate take-back system
(See Environmental Considerations in this manual)

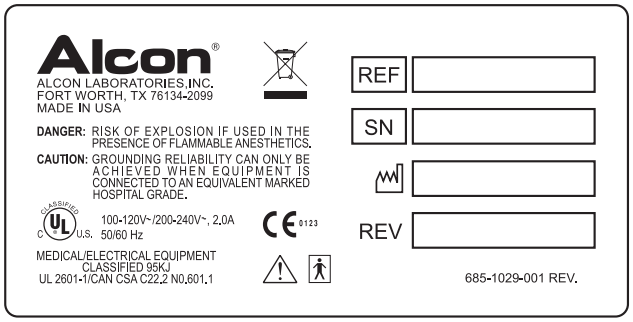

Figure 1-4. *OcuScan*® RxP LABELS AND ICONS - Shown here are the assorted labels and icons printed on the console and components.

IOL CALCULATION FORMULAS

Description of common variables :

AL: Axial length measured
K: Average diopter power of the cornea = (K1 + K2) / 2
R: Curvature of the cornea in mm = 337.5 / K (in diopters)
ACD: Post-operative anterior chamber depth is the value entered in the IOL file. The value is supplied by the IOL manufacturer and is used by the BINKHORST II formula except where correction is made to ACD.

KERATOMETRY

On axis 0, K1 = 28 D to 62 D in diopters
On axis 0, K2 = 28 D to 68 D in diopters
On axis 90°, K2 = 5 mm to 13 mm radius of curvature in mm
K = (K1 + K2) / 2
K in diopters, K = 337.5 / Kmm
Refraction index used: 1.3375

BIOMETRY

AL = Axial length (17 to 40 mm)
L = Axial length

BINKHORST II VARIABLES :

LB2: Axial length corrected for Binkhorst II

LB2 = AL + 0.1984 mm

ACDbnk: Corrected anterior chamber depth only for the posterior chamber IOL.

If LB2 < 26, then ACDbnk = ACD (LB2 / 23.45)
If LB2 ≥ 26, then ACDbnk = ACD (26 / 23.45), i.e., ACDbnk = 1.1087 x ACD

NOTE: When the IOL TYP (type) is labeled anterior, the ACD value does not require correction. When the IOL TYP (type) is labeled posterior, the ACD value is corrected and the IOL power will change.

HOLLADAY VARIABLES :

L: Axial length in mm
Lhol: Axial length corrected for HOLLADAY
Lhol = L + 0.200 mm

SF: Surgeon Factor proper for HOLLADAY formula
SF = (0.5663 x A) - 65.60, where A = SRK Constant

This calculation per default is proposed when parameters are entered in IOL files. If the operator modifies SF, it is this new coefficient which will be used.

CAhol: Anterior chamber corrected for HOLLADAY

Rag = R except if R < 7 mm, then Rag = 7 mm
AG = (12.5/23.45) L; i.e., AG = 0.533 x L, except if AG >13.5, then AG = 13.5 mm

$$ACDH = 0.56 + Rag - \sqrt{Rag^2 - \frac{AG^2}{4}}$$

CAhol = ACDH + SF

Common formulas for BINKHORST II and HOLLADAY :

R: Curvature of the cornea in mm = 337.5 / K (with K in diopters)
LC: Axial length corrected
CA: Post-operative anterior chamber
IOLam: IOL power for ametropia

For BINKHORST :
LC = LB2
CA = ACD for anterior chamber, or ACDbnk for posterior chamber

For HOLLADAY :
LC = Lhol
CA = CAhol

Formula which gives the IOL value depending on the desired target ametropia (or refraction) Tam:
IOLam = f (Tam)
if Tam = 0 then IOLam = IOLem (emmetropic)

$$IOLam = \frac{1336\,(1.336R - 0.3333LC - 0.001Tam\,(16.032R - 4LC + LC \times R))}{(LC - CA)\,(1.336R - 0.3333CA - 0.001Tam\,(16.032R - 4CA + CA \times R))}$$

Formula which gives the refraction value depending on the desired IOLam:
Tam = f (IOLam)

$$Tam = \frac{1336\,(1.336R - 0.3333LC) - IOLam\,(LC - CA)\,(1.336R - 0.3333CA)}{1.336\,(16.032R - 4LC + LC \times R) - 0.001IOLam\,(LC - CA)\,(16.032R - 4CA + CA \times R)}$$

HOFFER-Q FORMULAS:

P = IOL power in Diopters A = Axial length in mm
R = Refractive error at corneal plane Rx = Refractive error at spectacle
K = K Average in Diopters C = ACD: Anterior Chamber Depth in mm
pACD = personalized ACD (in lens constants)

Constants:
Refractive index of cornea = 1.336 Retinal thickness factor = 0
Vertex distance (glasses) = 12 mm

Hoffer Formula: IOL Power
$R = Rx/(1-0.012\ Rx)$
$P = (1336/(A - C - 0.05)) - (1.336/((1.336/(K + R)) - ((C + 0.05)/1000)))$

Hoffer Formula: Refractive Error
$R = (1.336/(1.336/(1336/(A - C - 0.05) - P) + (C+0.05)/1000))-K$

Hoffer Q Formula: Predicted ACD
$ACD = pACD + 0.3\ (A - 23.5) + (\tan K)^2 + (0.1\ M\ (23.5 - A)^2\ (\tan\ (0.1\ (G - A)^2)) - 0.99166$

For Predicted ACD:
If $A < 18.5$, then $A = 18.5$
If $A > 31.0$, then $A = 31.0$
If $A \leq 23$, then $M = +1$ and $G = 28$
If $A > 23$, then $M = -1$ and $G = 23.5$

SRK-II FORMULAS :

P = Emmetropic power
I = Desired IOL power
Rf = Refraction factor
L = Measured axial length (mm)
K = Averaged Keratometry (D)
A = SRK and SRK II A Constant

Emmetropic power: $P = A - 2.5\ L - 0.9\ K + C$

C = Correction with respect to original SRK formula where C = 0

C values according to the measured axial length :

If $L < 20$ mm, then C = 3
If $20 \leq L < 21$, then C = 2
If $21 \leq L < 22$, then C = 1
If $22 \leq L < 24.5$, then C = 0
If $L \geq 24.5$ mm, then C = –0.5

Ametropia values :

with: P = Emmetropia power
I = Desired IOL power
Rf = Refraction factor
Tam = Target Ametropia

Refraction = f(I): Tam = (P-I) / Rf where Rf = 1.25 if $P > 14$; Rf = 1 if $P \leq 14$

IOL = f(Tam): I = P – (Tam x Rf) where Rf = 1.25 if $P > 14$; Rf = 1 if $P \leq 14$

SRK-T FORMULAS :

L = Measured Axial length (mm)
Lcor = Corrected axial length (mm)
Rcor = Corneal Radius of curvature (mm)
K = Average K (D)
crwdest = Computed corneal width (mm)
ACDT = ACD-Constant from the A-Constant
ACDest = Estimated postoperative ACD for patient

Retinal thickness: Rethick = 0.65696 – 0.02029 x L

Lcor = L if $L \leq 24.2$
Lcor = $-3.446 + (1.716 \times L) - (0.0237 \times L^2)$ if $L > 24.2$

Rcor = $337.5 / K_D$ (with K in diopters)

crwdest = –5.41 + 0.58412 x Lcor + 0.098 x K

SqrootR1 = $(Rcor)^2 - (crwdest)^2 / 4$
if SqrootR1 < 0 then SqrootR1 = 0

Hest = $Rcor - \sqrt{SqrootR1}$

ACDT = 0.62467 x A – 68.747 (where A = SRK Constant)

ACDest = Hest + ACDT – 3.336

na = 1.336
C2 = 0.3333
C3 = L + rethick = 0.97971 x L + 0.65696
C4 = C3 – ACDest
C5 = (na x Rcor) – (C2 x ACDest)
C6 = (na x Rcor) – (C2 x C3)
C8 = (12 x C6) + (C3 x Rcor)
V = 12 vertex distance: lens/cornea
C9 = (12 x C5) + (ACDest x Rcor)

$$IOLam = \frac{1336 \times (C6 - (0.001 \times Tam \times C8))}{C4 \times (C5 - (0.001 \times Tam \times C9))}$$

Tam = targeted or desired postoperative refraction (D)

$$Tam = \frac{(1336 \times C6) - (IOLam \times C4 \times C5)}{(1.336 \times C8) - (0.001 \times IOLam \times C4 \times C9)}$$

HOLLADAY REVERSE SOLUTION OF SURGEON FACTOR

I = Power of IOL (Diopters)
K = Average K Reading (Diopters) = (K1 + K2) / 2
R = Average Corneal Radius (mm) = 337.5 / K
SPH = Sphere (Diopters)
CYL = Cylinder (Diopters)
Aref = Actual postoperative spheroequivalent refraction = SPH + (CYL/2)
Alm = modified axial length (mm) = AL + 0.200
V = vertex distance (mm) , Default Value = 12 mm
(when Aref < -4, or when Aref > +4, user must input vertex distance)
Rag = R, if r<7 mm, then Rag = 7 mm
AG = 12.5 x (AL / 23.5), if AG > 13.5 mm, then AG = 13.5

$$ACD = 0.56 + ag - \sqrt{Rag^2 - \frac{AG^2}{4}}$$

AQ = 0.3333 - (0.001 x Aref ((0.3333 x V) - R))
BQ = 0.001 x Aref x ((0.333 x Alm x V)-(R x (Alm-(1.336 x V))))-((0.333 x Alm)+(1.336 x R))
CQ1 = 0.001 x Aref x V x ((1.336 x R) - (0.3333 x Alm) + (Alm x R))
CQ2 = (1336 ((1.336 x R)-(0.333 x Alm) - CQ1)) / I
CQ3 = (1.336 x Alm x R) - (0.001336 x Aref x Alm x V x R)
CQ = CQ3 - CQ2
SF = (((-BQ) - SQRT ((BQ^2) - (4AQ x CQ)))/(2 x AQ)) - ACD

HAIGIS FORMULAS (optional)

IOL Power for given refraction (D_L):

$$D_L = \frac{n}{(L-d)} - \frac{n}{n/z - d} \quad \textit{where:} \quad z = D_C + \frac{R_X}{1 - R_X d_X} \quad \textit{where:} \quad D_C = \frac{n_C - 1}{R}$$

D_L = refractive power of IOL
D_C = refractive corneal power
R_X = desired refraction
n = 1.336 - refractive index of aequeous and vitreous
n_C = 1.3315 - fictitious refractive index of cornea
d_X = 12 mm - vertex distance between cornea and spectacles
R = average corneal radius
L = axial length measured by ultrasound
d = optical ACD

Refraction (R_X) for given IOL power:

$$R_X = \frac{q - D_C}{1 + d_X (q - D_C)} \quad \textit{where:} \quad q = \frac{n\,[n - D_L(L-d)]}{n\,(L-d) + d\,[n - D_L(L-d)]}$$

Optical ACD (d):

For AC ≠ 0: d = a0 + a1(AC) + a2(L)
For AC = 0: d = [a0 + u(a1)] +[a2 +v (a1)] (L)

AC = preoperative anterior chamber depth as measured by ultrasound
L = preoperative axial length as measured by ultrasound
u = -0.241
v = 0.139
a0, a1, and a2 are constants describing the implant IOL.

IOL Constants a0, a1, and a2:

Standard

a0 = 0.62467 (A) - 72.434; where A = A constant of the lens manufacturer
a1 = 0.4
a2 = 0.1

Optimized

In optimized mode, the constants a0, a1 and a2 are obtained by a separate optimization process. For each patient, the actual postop refraction is used to calculate the corresponding optical ACD. For all patients, these values are then correlated with the preop ultrasound measurements of the (acoustical) ACD and the axial length L. Double linear regression analysis yields the constants a0, a1 and a2. The Haigis Formula works best when optimized constants are used. *OcuScan*®RxP is shipped with Standard constants but user has the choice to enter their optimized constants.

NOTE: "R" in Haigis Formula is calculated using K1 and K2. But if K's are adjusted (normally done for eyes undergone Refractive surgery) using K-Adjust then K-Haigis is calculated for Haigis IOL power calculation.

Table 1-5
Lens Constant Conversion Table[4]

A CONSTANT (D)	Anterior Chamber Depth (mm)	Surgeon Factor (mm)
110.0	.30	-3.31
110.1	.36	-3.25
110.2	.41	-3.19
110.3	.47	-3.14
110.4	.53	-3.08
110.5	.59	-3.02
110.6	.65	-2.97
110.7	.70	-2.91
110.8	.76	-2.85
110.9	.82	-2.80
111.0	.88	-2.74
111.1	.94	-2.68
111.2	1.00	-2.63
111.3	1.06	-2.57
111.4	1.11	-2.51
111.5	1.17	-2.46
111.6	1.23	-2.40
111.7	1.29	-2.34
111.8	1.35	-2.29
111.9	1.40	-2.23
112.0	1.46	-2.17
112.1	1.52	-2.12
112.2	1.58	-2.06
112.3	1.64	-2.00
112.4	1.70	-1.95
112.5	1.76	-1.89
112.6	1.81	-1.84
112.7	1.87	-1.78
112.8	1.93	-1.72
112.9	1.99	-1.66
113.0	2.05	-1.61
113.1	2.11	-1.55
113.2	2.16	-1.50
113.3	2.22	-1.44
113.4	2.28	-1.38
113.5	2.34	-1.32
113.6	2.40	-1.27
113.7	2.46	-1.21
113.8	2.51	-1.16
113.9	2.57	-1.10
114.0	2.63	-1.04
114.1	2.69	-.98
114.2	2.75	-.93
114.3	2.81	-.87
114.4	2.86	-.82
114.5	2.92	-.76
114.6	2.98	-.70
114.7	3.04	-.64
114.8	3.10	-.59
114.9	3.16	-.53

A CONSTANT (D)	Anterior Chamber Depth (mm)	Surgeon Factor (mm)
115.0	3.21	-.48
115.1	3.27	-.42
115.2	3.33	-.36
115.3	3.39	-.31
115.4	3.45	-.25
115.5	3.51	-.19
115.6	3.56	-.14
115.7	3.62	-.08
115.8	3.68	-.02
115.9	3.74	.03
116.0	3.80	.09
116.1	3.86	.15
116.2	3.91	.20
116.3	3.97	.26
116.4	4.03	.32
116.5	4.09	.37
116.6	4.15	.43
116.7	4.21	.49
116.8	4.26	.54
116.9	4.32	.60
117.0	4.38	.66
117.1	4.44	.71
117.2	4.50	.77
117.3	4.56	.83
117.4	4.62	.88
117.5	4.67	.94
117.6	4.73	1.00
117.7	4.79	1.05
117.8	4.85	1.11
117.9	4.91	1.17
118.0	4.96	1.22
118.1	5.02	1.28
118.2	5.08	1.34
118.3	5.14	1.39
118.4	5.20	1.45
118.5	5.26	1.51
118.6	5.32	1.56
118.7	5.37	1.62
118.8	5.43	1.68
118.9	5.49	1.73
119.0	5.55	1.79
119.1	5.61	1.85
119.2	5.66	1.90
119.3	5.72	1.96
119.4	5.78	2.02
119.5	5.84	2.07
119.6	5.90	2.13
119.7	5.96	2.19
119.8	6.02	2.24
119.9	6.07	2.30

(continued on next page...)

Table 1-5
Lens Constant Conversion Table

(...continued from previous page)

A CONSTANT (D)	Anterior Chamber Depth (mm)	Surgeon Factor (mm)
120.0	6.13	2.36
120.1	6.19	2.41
120.2	6.25	2.47
120.3	6.31	2.53
120.4	6.37	2.58
120.5	6.42	2.64
120.6	6.48	2.70
120.7	6.54	2.75
120.8	6.60	2.81
120.9	6.66	2.87
121.0	6.72	2.92
121.1	6.77	2.98
121.2	6.83	3.04
121.3	6.89	3.09
121.4	6.95	3.15
121.5	7.01	3.21
121.6	7.07	3.26
121.7	7.12	3.32
121.8	7.18	3.38
121.9	7.24	3.43
122.0	7.30	3.49
122.1	7.36	3.55
122.2	7.42	3.60
122.3	7.47	3.66
122.4	7.53	3.72
122.5	7.59	3.77

A CONSTANT (D)	Anterior Chamber Depth (mm)	Surgeon Factor (mm)
122.6	7.65	3.83
122.7	7.71	3.89
122.8	7.77	3.94
122.9	7.82	4.00
123.0	7.88	4.05
123.1	7.94	4.11
123.2	8.00	4.17
123.3	8.06	4.22
123.4	8.12	4.28
123.5	8.18	4.34
123.6	8.23	4.39
123.7	8.29	4.45
123.8	8.35	4.51
123.9	8.41	4.56
124.0	8.47	4.62
124.1	8.53	4.68
124.2	8.58	4.73
124.3	8.64	4.79
124.4	8.70	4.85
124.5	8.76	4.90
124.6	8.82	4.96
124.7	8.88	5.02
124.8	8.93	5.07
124.9	8.99	5.13
125.0	9.05	5.19

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LAST PAGE OF SECTION

SECTION TWO
DESCRIPTION

General Description

The *OcuScan*® RxP Measuring System is a diagnostic tool used by ophthalmic surgeons for pre and post-operative diagnostic examinations addressing cataract and refractive surgery needs. The standard system consists of a main console, a footswitch, an external power supply, and a biometry probe. Optional pachymetry software can be installed along with a pachymetry probe that will enable the system to be used for taking corneal thickness measurements. An optional compact flash card is used to save patient records.

The standard viewing display/touch screen is an 800 x 600 SVGA LCD. Also available to the user is an external SVGA output port that can be used to connect an external SVGA monitor. A built-in thermal text printer is used to provide hard copies of screens and reports. An external power supply provides power for the console operation.

Front Panel

The 800 x 600 SVGA LCD with touch screen is on the console front panel (see Figure 2-1). Beneath the LCD display is an internal thermal printer compartment. To the left of the printer is the speaker, and to the right is the standby switch with an LED that indicates standby mode when OFF. Probe holders are located on each side of the front panel. **NOTE: It is recommended to place probes in the holders in the position shown in Figure 2-1. The probe tips should be pointing up.**

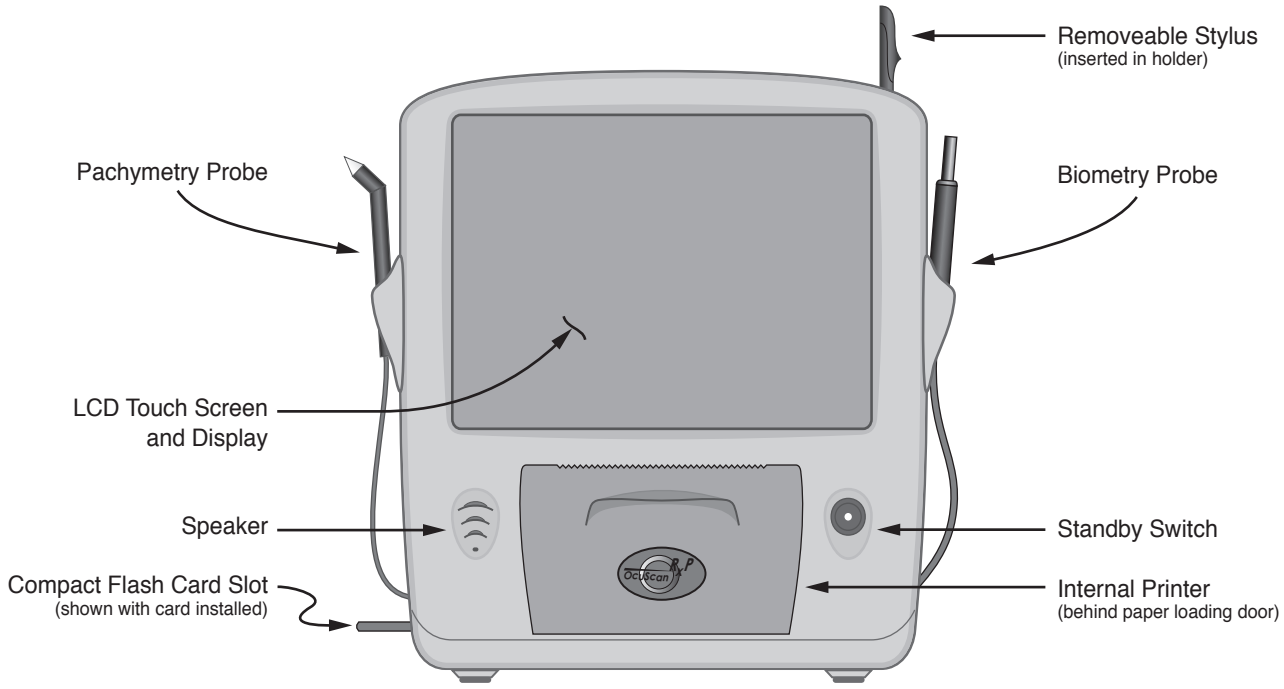


Figure 2-1 FRONT PANEL - The front panel contains an LCD touch screen, a standby switch, a speaker, and printer.

Front Panel Components (see Figure 2-1)

- ***LCD Touch Screen and Display***
  User interface to the system is via the built-in LCD touch screen. Waveforms, patient data, and functional control keys are shown on the display.

- ***Standby Switch with LED***
  With power connected there are three modes the unit can be in: normal mode, screen saver mode, and standby mode. While in normal mode, if the footswitch or touch screen is not activated for 10 minutes, the system will go into screen-saver mode (floating icon). If it is still not activated for another 15 minutes then it will go into standby mode (blank screen).

  - While system is in screen-saver mode or normal mode, pressing the standby switch sets the system to standby mode.

  - While in standby mode, pressing the standby switch returns the system to normal mode without going through the boot-up sequence.

  - While in screen-saver mode, tapping the touch screen or footswitch returns the system to normal mode.

  - On systems 685-0000-502 and above (see REF number on label), pressing and holding the standby switch for 7 seconds then releasing will reset (reboot) the system.

- ***Speaker***
  Used to signal the acquisition of readings. A beep is emitted each time a reading is stored. In Pachymetry S-Auto mode, a voice confirmation of the acquired measurement value is provided. Audio feedback mode provides the user with feedback of signal integrity.

- ***Internal Printer***
  The current screen or a full report of the patient data can be printed on the internal printer.

- ***Probe Holders***
  The console contains probe holders on both sides of the viewing screen to hold Pachymetry probe on one side and Biometry probe (with or without sleeve) on the other side.

- ***Stylus***
  Above the touch screen is a hole used to store the plastic stylus. Either the stylus or your finger can be used to select a function or to enter data.

  CAUTION

  Do not use a sharp object in place of the stylus as it may damage the touch screen.

Rear Panel

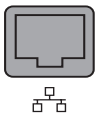
The rear panel contains the power input connector and connectors to interface with system accessories (see Figure 2-2). Labels on the rear panel identify each of the components, and also warn the operator of possible dangers.

Rear Panel Components

- ***Power Input Connector***
  +24 VDC power enters the rear panel through an 8-pin din connector.

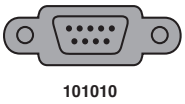
- ***External SVGA Video Output Connector***
  The system provides a standard SVGA output connector for an optional monitor.

- ***Footswitch Connector***
  The footswitch connects to this Mini Din connector.



- ***Ethernet Connector***
  The Ethernet interface on the rear panel is used for network connection.

- ***USB Connector***
  The USB bus connection is used to store and retrieve patient data to and from a PC.



- ***RS232 Connector***
  RS 232 serial communication connects the system to an external PC for service use.

- ***Biometry Probe Connector***
  Use this connector to plug in the Biometry probe.

- ***Pachymetry Probe Connector***
  Use this connector to plug in the Pachymetry probe.

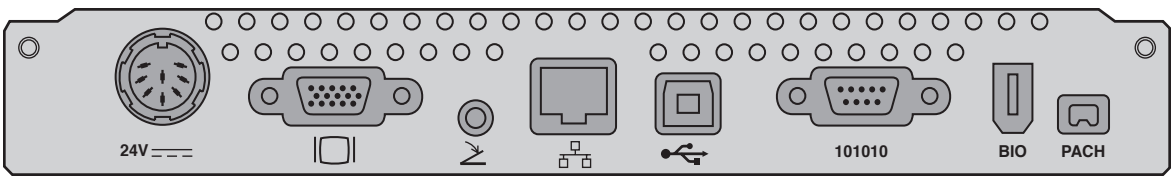


Figure 2-2 REAR PANEL - The rear panel contains a variety of connectors used to connect power, handpieces, the footswitch, and accessories.

Flash Card Slot

The side panel contains a flash card slot where a Compact Flash card can be inserted for storing patient data or upgrading the system software (see Figure 2-3). The *OcuScan*® RxP Measuring System is a computerized machine that operates under software control. If and when software upgrades are required, the new program can be installed into the system through the use of a Compact Flash card. For instructions on installing software upgrades, refer to "Installing Optional Software and Upgrading System Software" in Section One of this manual.

Eye Model

In the base of the console, behind the touch screen, is a contact-type eye model used for the probe check (see Figure 2-3). A probe check determines system functionality and tests probe strength by measuring the Eye Model axial length. The eye model is designed to display traces to simulate peaks for contact cornea, anterior of lens, posterior of lens, and retina with a triangular shape simulating the sclera. Refer to Section Three: Probe Check for a detailed description on how to perform a probe check.

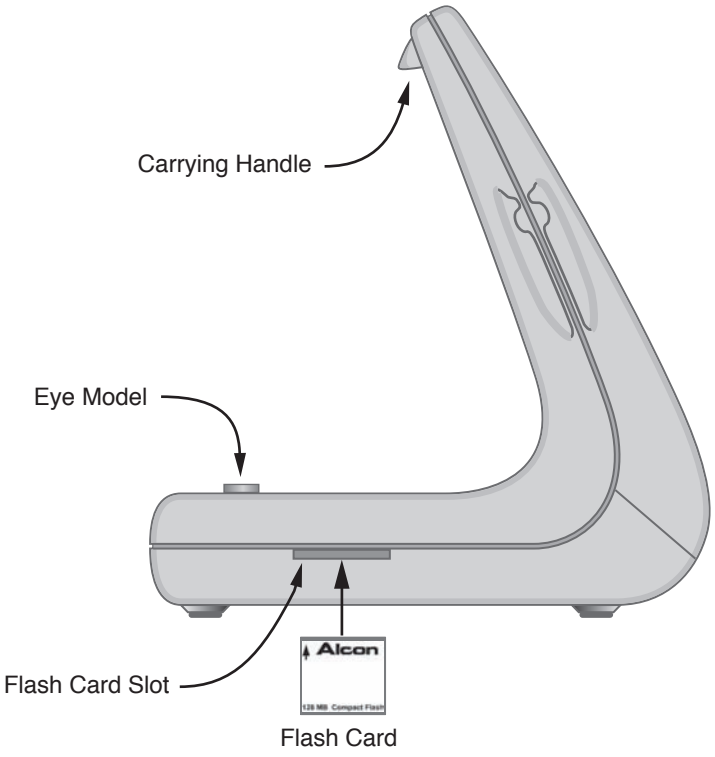


Figure 2-3 SIDE PANEL - The left side of the *OcuScan*® RxP Measuring System contains the Flash Card slot. Compact Flash cards are memory devices that can be used to save patient data or upgrade the system software.

Footswitch

The footswitch allows hands free initiation of the system control function.

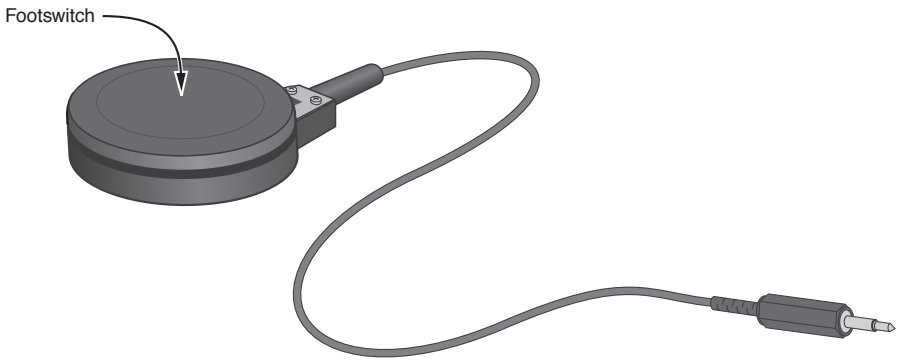


Figure 2-4 FOOTSWITCH - The *OcuScan®* RxP footswitch plugs into the rear panel.

Biometry Footswitch Functions

- *Automatic Mode* - To obtain biometry measurements in automatic mode, press and hold the footswitch while aligning the probe on the eye until the desired waveform or trace is obtained. It may be necessary to adjust the gain to obtain an acceptable waveform. At this point hold the probe steady and release the footswitch to obtain ten automatic measurements.

  If the measurement is not locking (possibly due to one of the signal amplitudes not meeting the required criteria), pressing and releasing the footswitch within 0.5 seconds will Force Freeze the measurement. After ten readings are obtained, the gates are automatically placed on the echograph, and the measurement is displayed in the reading box.

  The user can also move through the measurements by pressing and releasing the footswitch. Once a measurement is selected, holding the footswitch for 3 seconds will delete that measurement. When a measurement is deleted the system will go into Running-Saving state to acquire a new measurement. The above process can be repeated to delete and retake additional measurements one at a time.

- *Manual Mode* - To obtain a measurement, press and release the footswitch to activate the ultrasound. Place the probe on the eye and, when the desired waveform is displayed, press and release the footswitch to save the measurement. The operator can repeat this procedure nine more times, at which time gates are automatically placed on the echograph, and the measurement is displayed in the reading box.

Pachymetry Footswitch Functions

- *Automatic Mode* - In automatic mode, a thickness measurement is initiated by pressing a position button on the Pachymetry scan screen or by pressing and releasing the footswitch. The position button will start blinking indicating that the system is ready to take a measurement. In Map 1 or 2, hold the Pachymetry probe perpendicular to the cornea at the position that corresponds to the position button. The system will take a reading then move to the next location and start blinking indicating that it is ready for the probe to be placed at that location. After the system acquires the thickness readings for several positions, pressing the footswitch deletes the previous position's value. The position button will start blinking indicating that it is ready to acquire new data for that position.

  In Single Point, quickly pressing and releasing the footswitch will step back through the measurements. A selected measurement starts blinking and turns pink if the user does not press the footswitch again within 3 seconds. Pink readings are deleted and new measurements can be taken. If the user has pressed the footswitch within 1 second, then the blinking would move to the previous location without turning the current location to pink. After all the configured readings have been taken for one eye (OD), pressing and holding the footswitch 5 seconds selects the other eye (OS). When the system has switched to the other eye, pressing and releasing the footswitch will cause the 1st position to start blinking indicating that the system is ready to take the measurement.

- *Manual Mode* - In Manual mode, the position button starts blinking by pressing the footswitch. Holding the probe perpendicular on the corneal position displays the current thickness. Pressing the footswitch locks the reading for that position and advances to the next position.

Probes and Probe Holders

The *OcuScan®* RxP Measuring System comes with probe holder cradles on each side of the viewing screen where the Biometry and Pachymetry probes are placed when they are not being used. The holder for the Biometry probe is on the right side of the monitor while the Pachymetry probe the holder is on the left.

Three methods of using the Biometry probe can be employed (see Figure 2-5). It can be held with or without its applicator for contact scans, it can be removed from its applicator for immersion scans, or it can be removed from its applicator and placed in a slit lamp adapter.

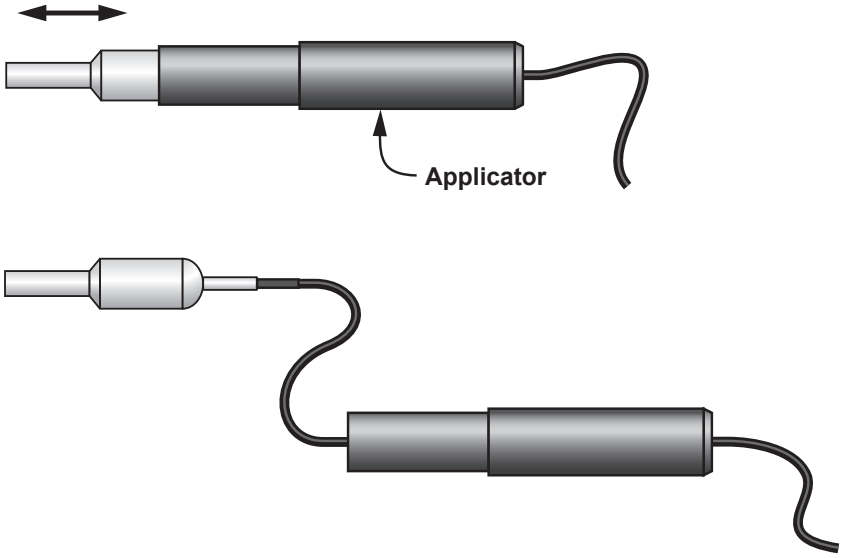


Figure 2-5 **BIOMETRY PROBE - Three methods of using the biometry probe are employed in biometry. In the upper illustration the probe is inserted into its spring-loaded applicator. This applicator applies a consistent light pressure to the cornea for scanning. In the lower illustration, the probe is removed from its applicator and can be placed in a slit lamp adaptor or used in an immersion shell.**

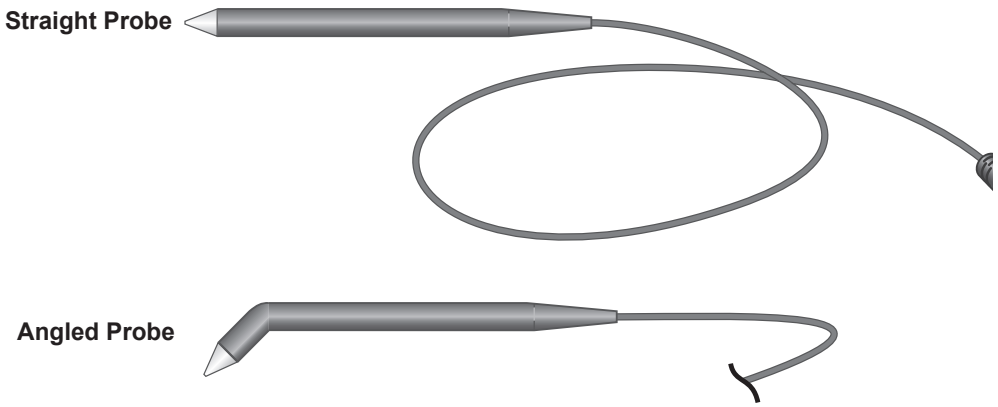


Figure 2-6 **PACHYMETRY PROBE - The optional Pachymetry probe fits comfortably into the operator's hand for effortless corneal thickness measurements. Two models are available: straight and angled (45°).**

External Power Supply

The *OcuScan®* RxP Measuring System is powered by one of the two external, universal power supplies shown in Figure 2-7. These supplies provide a DC voltage of 24 V, and a minimum of 3.3 A to the console. They require a steady state input voltage in the range of 100-120/200-240 VAC, 2 A at 50/60 Hz. These are auto-ranging power supplies that automatically adjust to any voltage within the range.

NOTE: The power cord used to connect the power supply to the wall outlet is shipped with systems for use in the U.S.A. and Canada only. For other countries, a power cord with appropriate ratings and national safety agency approval must be used.

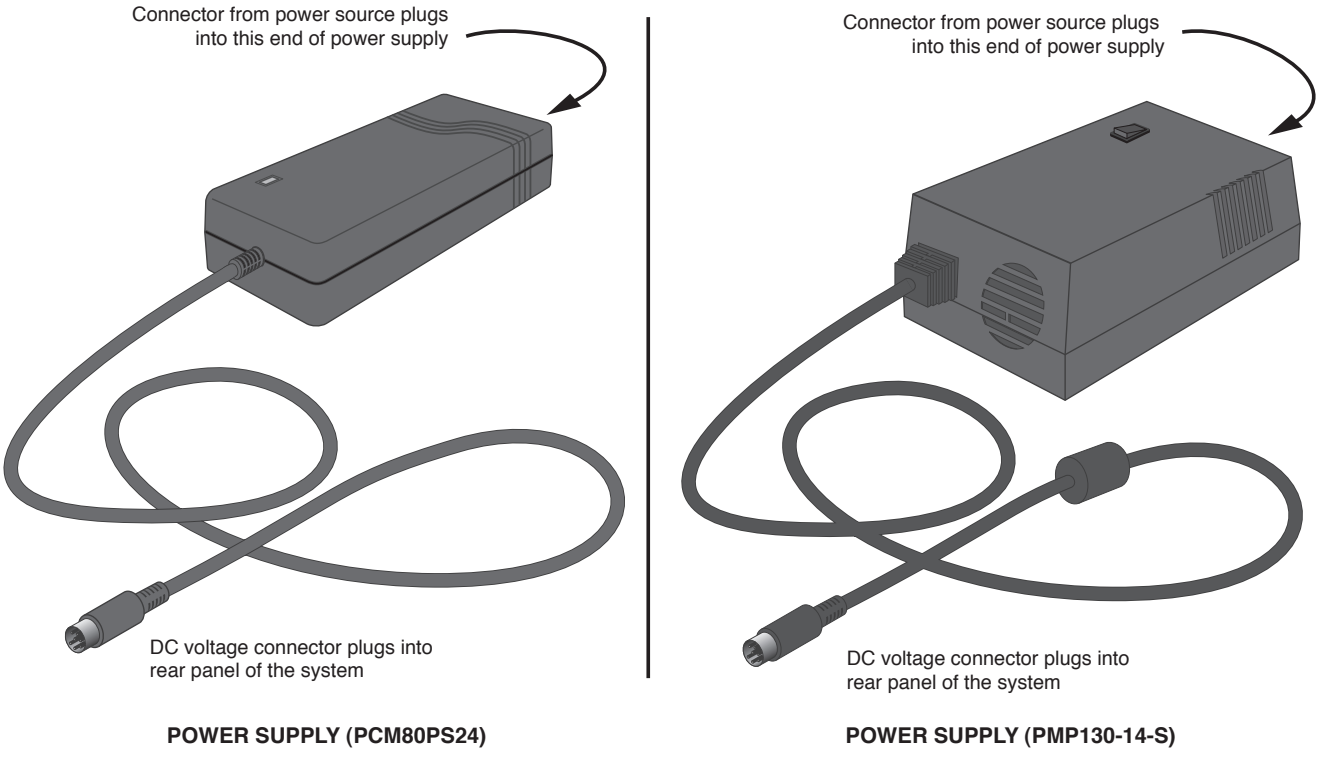


Figure 2-7 EXTERNAL POWER SUPPLY - The *OcuScan®* RxP Measuring System is powered by an external power supply.

KEYBOARDS

When entering data into the various data fields, the system will display a keyboard on the touch screen as shown in Figure 2-8. The first keyboard shown is the default with lowercase letters. The following keyboards are displayed when the circled keys are tapped on the touchscreen.

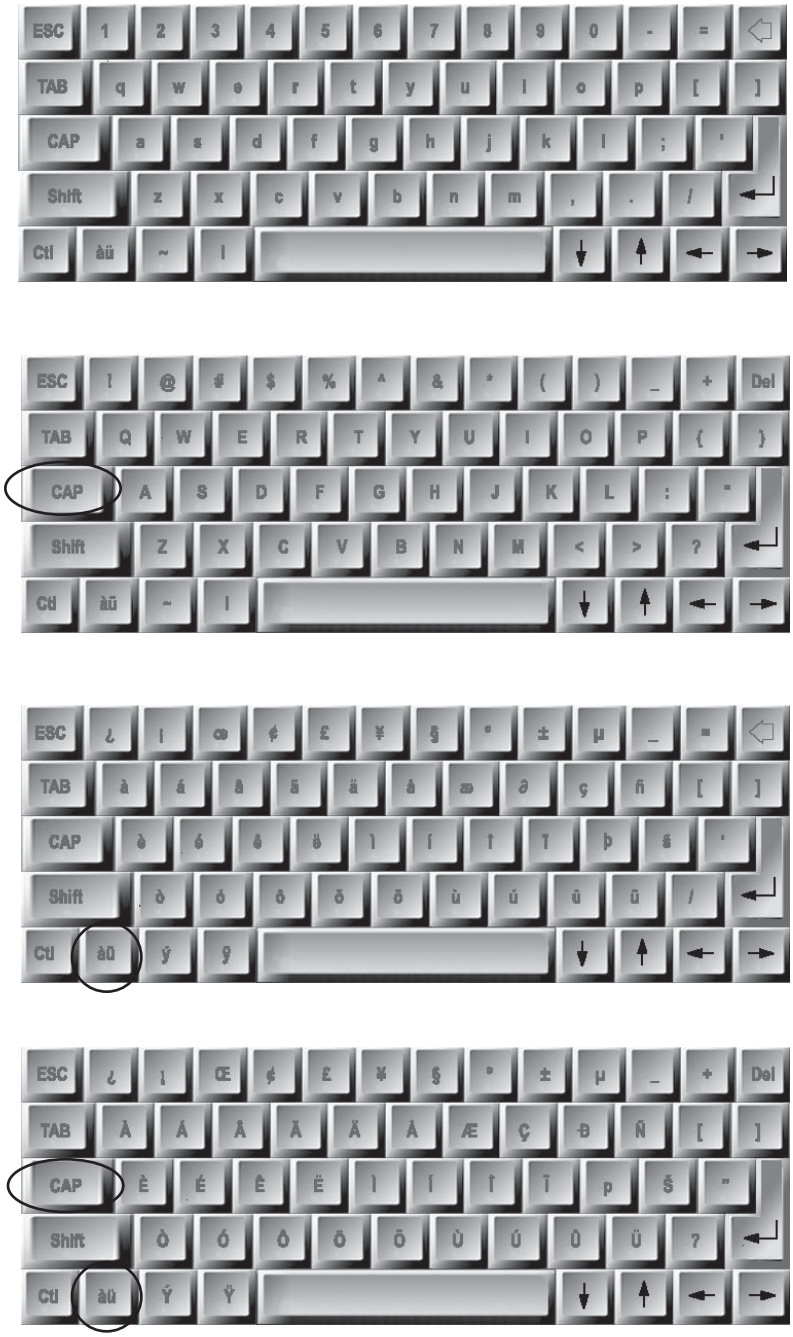


Figure 2-8 KEYBOARDS DISPLAYED ON THE TOUCHSCREEN - Four keyboards are available to enter patient data.

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SECTION THREE
OPERATING INSTRUCTIONS

INTRODUCTION

This section of the manual is written to help you learn to operate the *OcuScan*® RxP Measuring System. The operating instructions are written with the assumption that you have no previous experience with the *OcuScan*® RxP Measuring System and start at system power up then continue on through System Setup, Biometry Presets, Patient Information, and finally Biometry Scans. If the optional Pachymetry software is installed, instructions are also given for pachymetry setup and scanning. The following flowchart shows the structure of the *OcuScan*® RxP software and gives you an overall view of how to navigate in the system.

NOTE: Pachymetry is an optional item that must be ordered in addition to the standard Biometry function. See Section Six: Accessories and Parts for information on ordering the Pachymetry option.

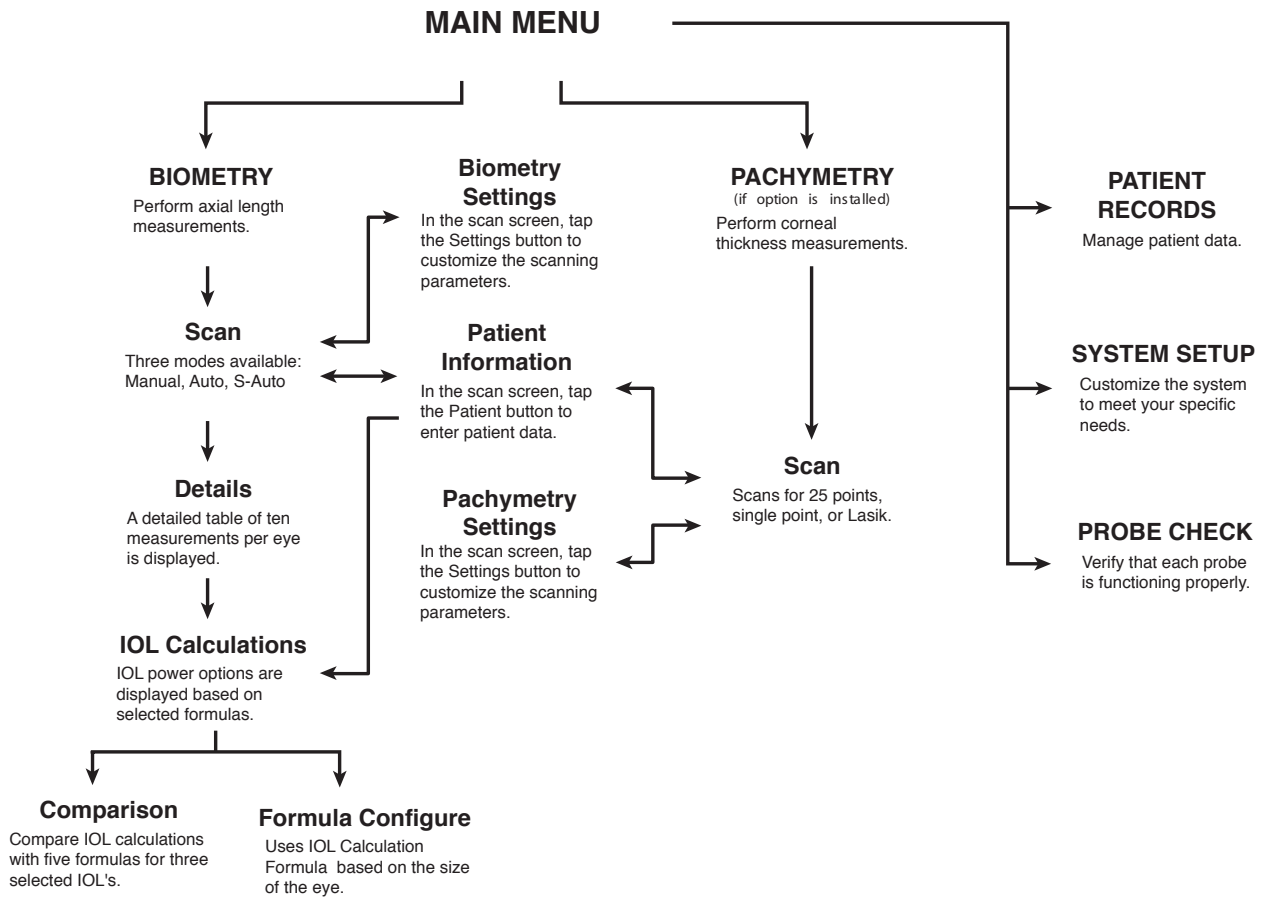


Figure 3-1 FUNCTIONAL FLOWCHART - This flowchart shows the sequential functions of the *OcuScan*® RxP Measuring System.

SYSTEM POWER-UP

When power is applied to the system, a power-up screen appears containing the *OcuScan®* RxP logo. During the power-up state the system performs self-tests for about three seconds. If any of the self-tests fail, a message appears on the bottom-half of the screen to notify the user. If the self-test failure is a prompt, the user can continue after acknowledgment by pressing the OK key. If it is a system failure, the user cannot transition out of the screen. After successfully completing the self-tests, the Menu screen appears.

It is not necessary to turn the system OFF. A "Screensaver" mode is activated after the screen and footswitch have been inactive for ten minutes. Figure 3-2 shows the screensaver display. Tapping the screen will deactivate the screensaver. If the system is inactive for another 15 minutes after entering screensaver mode, the system enters the standby mode (or sleep mode) and the screen will go blank. Standby mode can also be entered by pressing the Standby switch on the front panel.

System Reset

Systems with REF number 685-0000-502 can be reset by holding the Stand-by switch for 7 seconds or longer then releasing it. These actions will restart the system as in the power-up cycle.

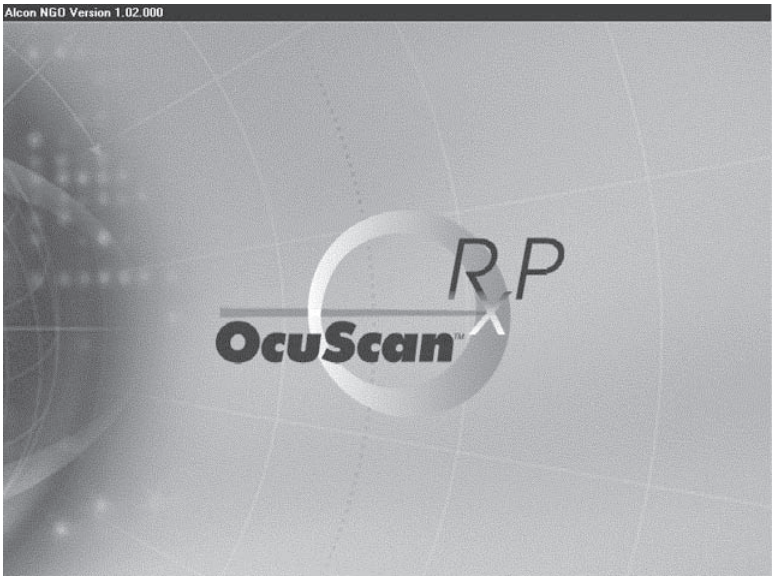


Figure 3-2 ***OCUSCAN®* RxP SCREENSAVER DISPLAY - The screensaver display appears after the system has been inactive for ten minutes.**

The Menu Screen

From the Menu screen the user may go directly to the Biometry screen (or optional Pachymetry screen if installed). Alternatively, the user may elect to view the System Setup screen, Patient Records, or the Probe Check screen.

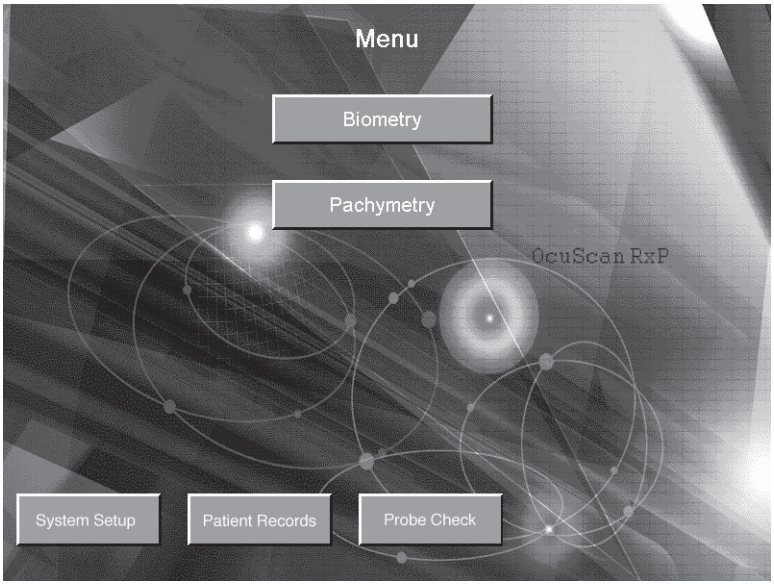


Figure 3-3 MENU SCREEN - After the system transitions to the Menu screen the user can choose from the selections shown here (shown with Pachymetry option installed).

Using the Touch Screen

The *OcuScan*® RxP Measuring System uses a touch screen user interface with the system. The stylus provided with the system is the recommended tool to use when touching the screen to make selections. A holder is located at the top of the system to conveniently store the stylus. Selections are made by lightly tapping the stylus on the screen.

SYSTEM SETUP

The first time a new system is powered up it is important to configure it with your local information (date, time, etc.). To fill in the System Setup data, follow the instructions below.

1 With the external power supply plugged into a power plug (110-120/220-240 VAC), and its 24 VDC cable plugged into the *OcuScan®* RxP rear panel, the system will automatically turn on. (For systems using power supply PMP130-14-S, press the toggle switch on the power supply to turn the system on.) The Power-Up screen appears and an LED illuminates in the middle of the standby switch button to indicate that power is turned ON. After the *OcuScan®* RxP Measuring System performs a quick system self-test, the Menu screen appears on the display monitor (see Figure 3-3).

2 From the Menu screen select ***System Setup***.

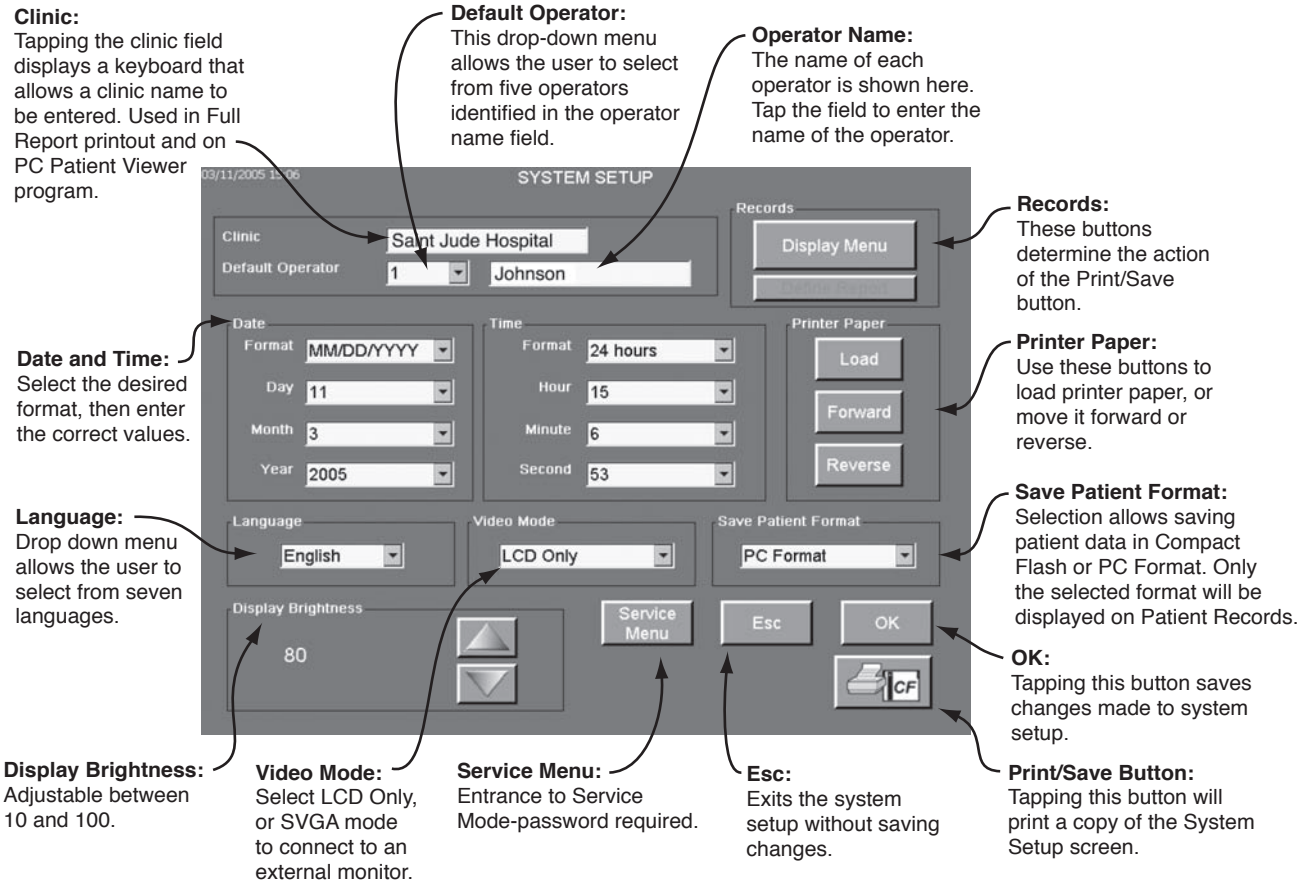


Figure 3-4 SYSTEM SETUP SCREEN - The System Setup screen enables the user to configure the system as needed. This screen is also used to load paper in the internal printer.

3 Using the stylus, touch the ***Clinic*** box; a keyboard appears on the screen. Using up to 20 characters, type the name of your facility, then press OK. The name of your facility appears in the Clinic box.

4 Select the Operator number from the drop down menu, then enter names for up to five operators. To enter a name, touch the text box next to ***Default Operator*** and a keyboard appears on the screen. Using up to 20 characters type the name, then press ***OK***. Press the ***Default Operator*** arrow until the desired number (1 to 5) is reached.

5 In the ***Date*** field, select the ***Format*** you desire to have the date displayed in from the following list, then select the current ***Day***, ***Month***, and ***Year***.
- *MON/DD/YYYY* - the month is shown alphabetically (JAN, FEB, etc.), the day and year numerically.
- *DD/MON/YYYY* - the day is shown numerically, the month alphabetically, and the year numerically.
- *MM/DD/YYYY* - the month, day, and year are shown numerically.
- *DD/MM/YYYY* - the day, month, and year are shown numerically.

6 In the ***Time*** field, select the ***Format*** you desire to have the time displayed in, then select the current ***Hour***, ***Minute***, and ***Second***.

7 In the ***Language*** field select the language you desire on the information screens.

8 The ***Video Mode*** field contains two selections in the drop down menu: LCD Only, or SVGA. Use the SVGA selection to enable the output to an external video monitor in addition to the LCD. If an external SVGA monitor is not used, it is recommended to select LCD only mode.

9 In the ***Display Brightness*** field adjust the optimum video brightness level for the room environment.

The Print/Save Button

The **Records** field contains two buttons that set the action of the Print/Save button that is displayed in most of the working screens. Pressing the top button toggles through the following options:

- Display menu - Displays the options window shown in Figure 3-5.
- Full Report and Save - Prints a full report (see Figure 3-6) and saves the data to the current patient's records (if a Compact Flash card is inserted).
- Current Screen - Prints the current screen only.
- Full Report - Prints a full report for the current patient.

10 Press and release the top button in the Records field to cycle through the options. Stop on "Full Report" or "Full Report and Save."

When “Full Report” or “Full Report and Save” have been selected, the Define Report button becomes active. Pressing the button opens a window that allows the user to select which items shown in Figure 3-5 will be printed each time the print button is pressed.

When saving a file that has already been saved, the system will provide the following options:

- Overwrite the existing files - overwrites patient's file with new data created since the last save.
- Save as new file - Saves data in a new file and adds an extension number to the name. For example: file named 007 will be saved as 007-1.
- Esc - returns to the previous screen without saving data.

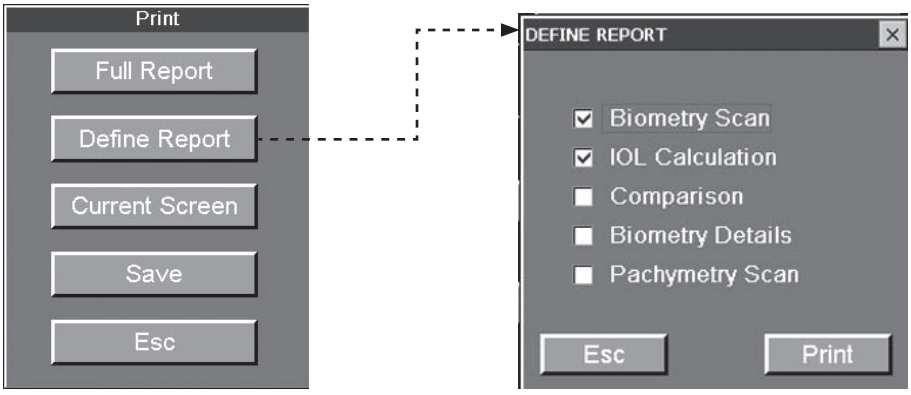
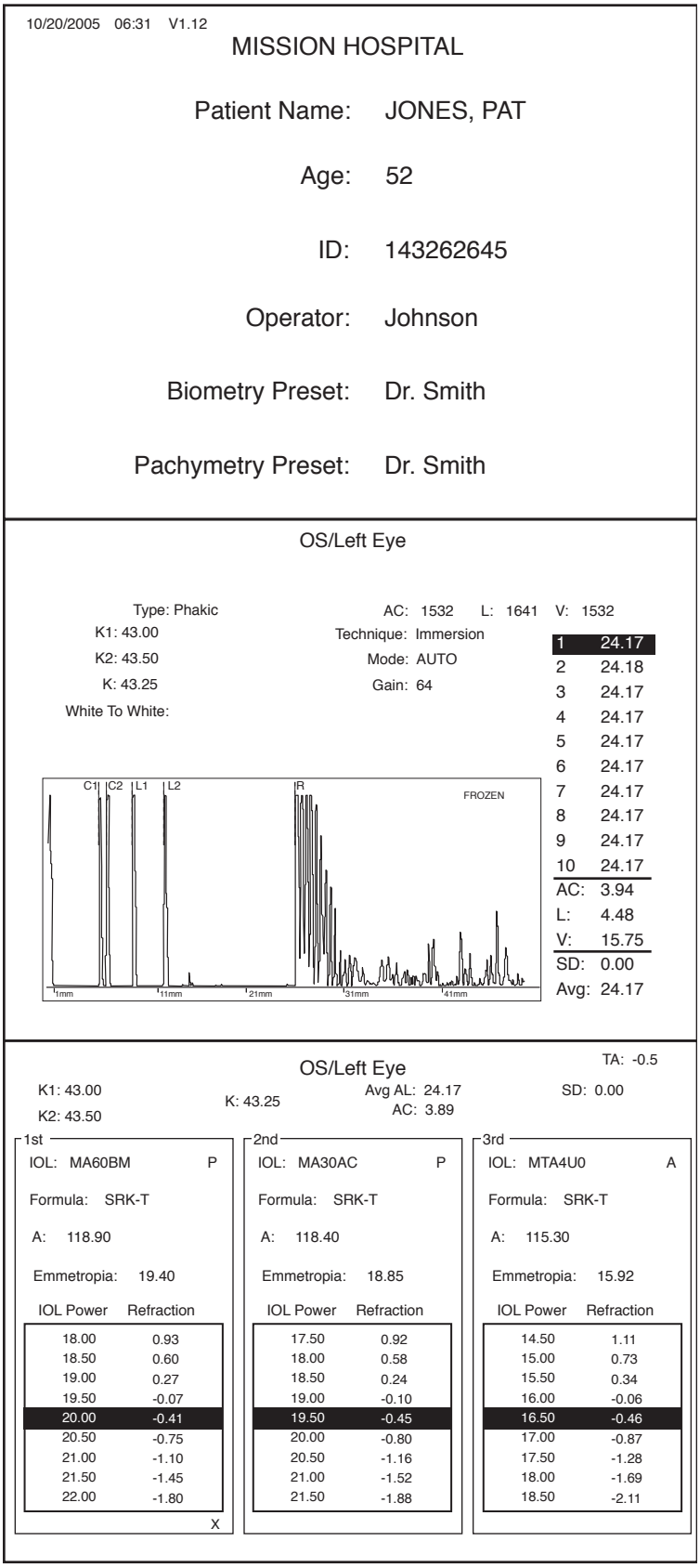


Figure 3-5 **DISPLAY MENU AND DEFINE REPORT POP UP WINDOWS - Choosing Display Menu from the Records selections allows instant access to the Print pop up window when the Print/Save button is pressed. The Define Report window allows you to select the specific data to be printed.**

Figure 3-6. FULL REPORT PRINTOUT
The Full Report depends upon measurements taken and K values entered. Data must be present in order for a report to be printed. If measurements were taken then the printout will contain most of the Scan screen information. The Calculation screen is printed if K values were entered. Pachymetry screens are printed if pachymetry measurements were taken for the same patient.

This figure shows a printout of the Full Report for a patient who had measurements taken for the left eye only. K values were entered so the IOL Calculation screen was also printed showing the various selections of IOL's and formulas used.



10/20/2005 06:31 V1.12

MISSION HOSPITAL

Patient Name: JONES, PAT

Age: 52

ID: 143262645

Operator: Johnson

Biometry Preset: Dr. Smith

Pachymetry Preset: Dr. Smith

OS/Left Eye

Type: Phakic
K1: 43.00
K2: 43.50
K: 43.25
White To White:

AC: 1532 L: 1641 V: 1532
Technique: Immersion
Mode: AUTO
Gain: 64

1	24.17
2	24.18
3	24.17
4	24.17
5	24.17
6	24.17
7	24.17
8	24.17
9	24.17
10	24.17
AC:	3.94
L:	4.48
V:	15.75
SD:	0.00
Avg:	24.17

OS/Left Eye

TA: -0.5

K1: 43.00
K2: 43.50
K: 43.25
Avg AL: 24.17
AC: 3.89
SD: 0.00

1st
IOL: MA60BM P
Formula: SRK-T
A: 118.90
Emmetropia: 19.40

IOL Power	Refraction
18.00	0.93
18.50	0.60
19.00	0.27
19.50	-0.07
20.00	-0.41
20.50	-0.75
21.00	-1.10
21.50	-1.45
22.00	-1.80

X

2nd
IOL: MA30AC P
Formula: SRK-T
A: 118.40
Emmetropia: 18.85

IOL Power	Refraction
17.50	0.92
18.00	0.58
18.50	0.24
19.00	-0.10
19.50	-0.45
20.00	-0.80
20.50	-1.16
21.00	-1.52
21.50	-1.88

3rd
IOL: MTA4U0 A
Formula: SRK-T
A: 115.30
Emmetropia: 15.92

IOL Power	Refraction
14.50	1.11
15.00	0.73
15.50	0.34
16.00	-0.06
16.50	-0.46
17.00	-0.87
17.50	-1.28
18.00	-1.69
18.50	-2.11

11 Tap the drop down menu in the *Save Patient Format* field and select the default format for saving patient data - Compact Flash or PC Format.

NOTE: The format selected in the System Setup screen determines what files appear in the Patient Records screen. For example: if PC Format is selected, then only those files saved in PC Format are displayed. If Compact Flash format is selected, then only files saved in Compact Flash format are displayed.

Compact Flash (Binary)
The Compact Flash format should be used when saving patient data for backup purposes. Files in this format cannot be viewed on a PC. The advantage of this format is that it maximizes the number of patient files that can be saved to a Compact Flash card. For example, a patient file containing biometry and pachymetry data for both eyes will have a file size of approximately 70 KB. Therefore a 128 MB Compact Flash card can hold a minimum of 1800 patient files saved in this format.

PC Format (Excel)
This format allows you to view the patient data on a Personal Computer (PC) using a Patient Viewer template that is included on the CD provided with the system. The file size is about twice the size of the Compact Flash file therefore only half as many patients can be stored on the Compact Flash card in this format as compared to the Compact Flash (binary) format.

For additional information, refer to *Copying Patient Data to a Personal Computer*.

12 Press ***OK*** to accept the changes and return to the Menu screen. Pressing the ***Esc*** key exits the System Setup screen without implementing any changes and returns to the Menu screen.

NOTE: The Service Menu is intended for use by service personnel only, therefore, a password is required to enter that area.

PATIENT RECORDS SCREEN

The Patient Records screen shown in Figure 3-7 allows the user to manage and select patient data. It is used to:

- Display patients currently saved to the Compact Flash card (if inserted).
- Sort the patients by identification number, last name, or first name.
- Remove a patient from the database.

NOTE: The Patient Records screen only displays patient records saved in the currently selected Patient Format in the System Setup screen. For example: if PC Format is selected, then only those files saved in PC Format are displayed. If Compact Flash format is selected, then only files saved in Compact Flash format are displayed.

The following actions are available by tapping the associated buttons on the patient records screen.

- **Select** - Loads the selected patient record, i.e., that patient becomes the current patient. Refer to "*Uploaded Patient Data*" for additional information.
- **Esc** - Exits the patient records screen without loading a patient.
- **Delete** - Deletes the selected records.
- **Refresh** - Updates the Patient table. This action is required when a different Flash card is inserted.
- **Ident** - Sorts the records by identification number.
- **Last Name** - Sorts the records by last name.
- **First Name** - Sorts the records by first name.

NOTE: When patient data is retrieved from storage, it displays only the patient data and measurements. IOL power calculations will depend on current selection of IOL's, formulas, and Target ametropia.

To select a patient, tap the desired patient entry with the stylus and it will be highlighted. To add new patients, refer to *Patient Setup for Biometry and Pachymetry*.

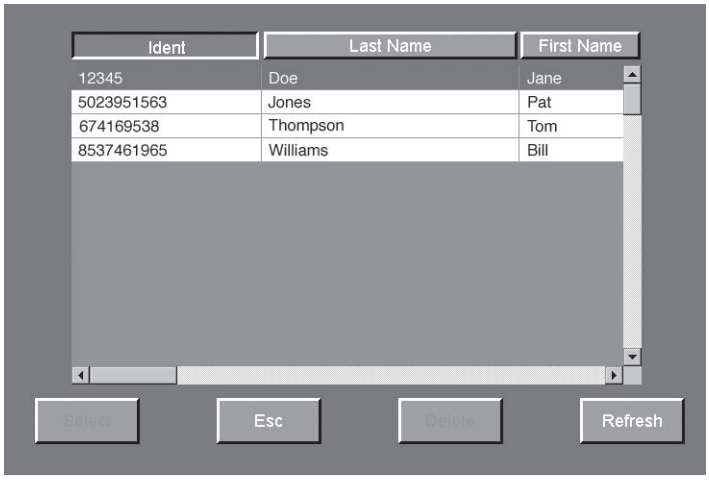


Figure 3-7 PATIENT RECORDS SCREEN
Tapping the Patient Records button on the main menu displays this screen. The user can select, sort, remove patient records, or refresh the listing from here.

The Patient Records screen only displays patient records saved in the currently selected Patient Format in the System Setup screen. For example: If PC Format is selected, then only those files saved in PC Format are displayed. If Compact Flash format is selected, then only files saved in Compact Flash format are displayed.

Uploaded Patient Data

Uploaded patient data is data that was previously saved to the Compact Flash card then uploaded back into the system for viewing. Uploaded patient data has the following characteristics:

- System settings that were saved along with patient data will be loaded back into the system.
- All up-loaded settings as well as measurement data will be highlighted in yellow and will only be highlighted on screens that have data.
- All fields in the Patient Information screen except Patient ID can be modified.
- If a setting is changed, a pop-up message is displayed warning the user that the current patient measurements will be deleted. If the new setting is accepted by tapping the checkmark, the software will reload the current system settings (last setting selected before upload), make the requested setting change, and restore the original default color. NOTE: System settings are changed in the Biometry and Pachymetry Presets screens.
- After a patient upload, the user can only delete all the measurements for an eye and not individual ones.
- Date and time when the patient records were last saved are shown.

PROBE CHECK

A probe check determines system functionality. For biometry, the probe check tests probe functionality by measuring the Eye Model axial length. The eye model is designed to display traces to simulate peaks for contact cornea, anterior of lens, posterior of lens, and retina with a triangular shape simulating the sclera.

Biometry Probe Check

1. From the Main Menu, tap the Probe Check button. The following message appears, "By entering any of the following options all patient data will be erased." If you have a current patient with unsaved data, tap the Esc button to go back and save the data then return to the probe check.

2. Tap the OK button to advance to the probe check.

3. Tap the Biometry button to select the biometry probe check. The biometry probe check screen appears as shown in Figure 3-8.

4. Verify that Technique is Contact. If not, tap the Settings field and select Contact mode to measure the eye model located at the back of the system.

5. Dip the tip of the biometry probe in water then place it on the eye model located at the rear of the system. **Note: Other eye models may give results different from those stated here.**

6. Select Auto mode.

7. Press the footswitch and wait for the system to take 10 readings.

8. Verify that the echogram has four strong echos representing the cornea (C1), front of the lens (L1), back of the lens (L2), and the retina (R).

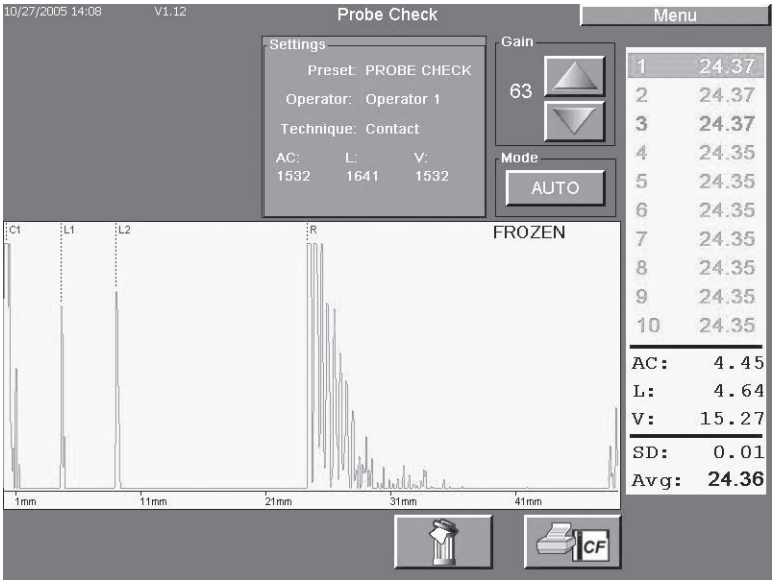


Figure 3-8. BIOMETRY PROBE CHECK SCREEN - This screen is used to verify that the biometry probe is functioning properly.

Pachymetry Probe Check

1. From the Main Menu, tap the Probe Check button. The following message appears, "By entering any of the following options all patient data will be erased." If you have a current patient with unsaved data, tap the Esc button to go back and save the data then return to the probe check.

2. Tap the OK button to advance to the probe check.

3. Tap the Pachymetry button to select the pachymetry probe check. The pachymetry probe check screen appears as shown in Figure 3-9.

4. Select Auto mode (if system is not in Auto mode already) and the 300-1100 range for the eye model at back of system.

5. Place a thin layer of water on top of the eye model then position the pachymetry probe perpendicular to the top surface of the eye model.

6. Press the footswitch and wait for the system to take all the configured readings for one eye. **Note: The probe must be perpendicular to the eye model in order for the system to detect a valid reading.**

7. Verify that the system takes a measurement for each scan # and all readings are relatively close to each other. **NOTE: A slight tilt of the probe may cause a larger Standard Deviation (SD).**

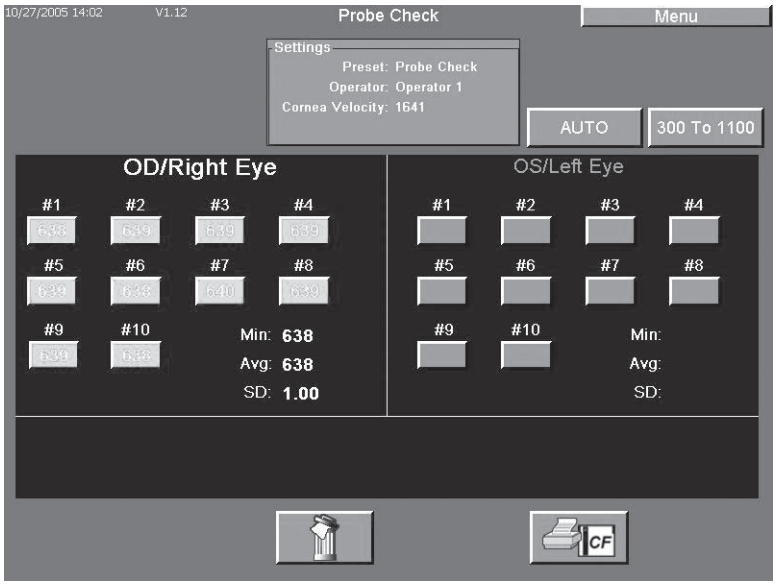


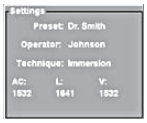
Figure 3-9. PACHYMETRY PROBE CHECK SCREEN - This screen is used to verify that the pachymetry probe is functioning properly.

BIOMETRY

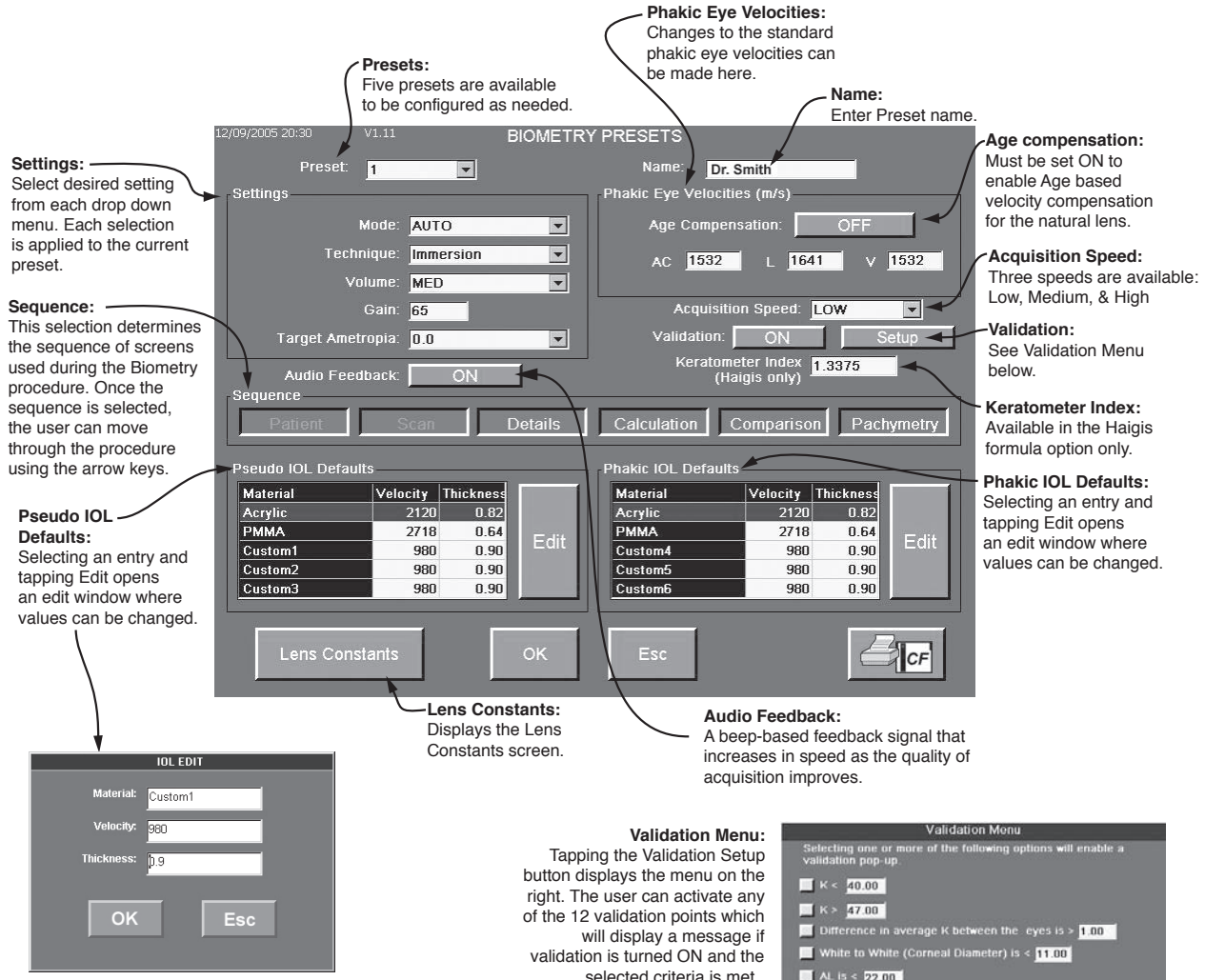
SETTING UP THE BIOMETRY PRESETS

The system allows up to five different preset configurations enabling the user to quickly select a particular setup for a patient based on eye type or surgeon preferences. The following steps show how to change and save a preset.

1. From the Menu screen, tap the Biometry button to enter the Biometry scan screen.



2. Tap anywhere in the Settings frame. The Biometry Presets screen appears as shown below in Figure 3-10.



Validation Menu: Tapping the Validation Setup button displays the menu on the right. The user can activate any of the 12 validation points which will display a message if validation is turned ON and the selected criteria is met.

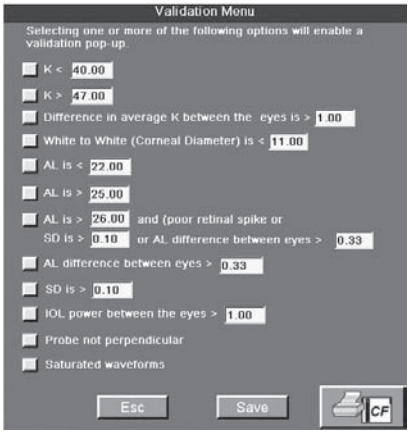


Figure 3-10 THE BIOMETRY PRESETS SCREEN
This screen allows the user to configure five different presets to select from when preparing for a biometry scan.

3. Tap the Preset down arrow to display the drop down menu. Five presets are available and each can be selected by tapping on the number.

4. Tap the Name field. If desired, enter a name for the preset using the keyboard displayed on the screen. Confirm the name by tapping OK.

Settings

The Settings frame contains selections to set the defaults for Mode, Technique, Volume, Gain, and Target Ametropia. The user can also select Audio Feedback, Age Compensation, Velocities for phakic eye, Acquisition Speed, and Validation. When a new patient is initiated in the patient screen, the defaults from the selected Setting are automatically activated, although Mode and Gain can be manually changed on the Scan screen.

5. Tap the **Mode** drop down menu (down arrow) and select the desired mode.

   The Mode setting has three options: Manual, Auto, or S-Auto (Super Auto). The factory default is set as Auto.

   Manual - In this mode the user unfreezes the system by pressing and releasing the footswitch, positions the probe on the eye, and looks for a good waveform. When a desired waveform is seen, the footswitch is pressed and released to save the measurement. Software criteria requires a minimum of cornea and retina peak detection to save the reading under Force Freeze condition. Force Freeze measurements are shown in smaller font and blue color.

   Auto - In this mode press and hold the footswitch, align the probe to get the best waveform and release the footswitch. If the software criteria for range and amplitude of peaks is met, then the system will automatically obtain ten readings. If there is difficulty in obtaining a measurement, the user can override the software criteria by initiating a force save by pressing and releasing the footswitch within a half-second. Force Freeze measurements are shown in smaller font and blue color. The user should review the peaks and gate locations to decide to retain or delete the Force Freeze measurements.

   S-Auto - Super Auto mode is similar to Auto mode except that it automatically adjusts the gain, and software criteria looks for beam perpendicularity.

6. Tap the **Technique** drop down menu and select the desired technique: Immersion or Contact. The default mode is Contact.

   Contact - In the Contact technique, readings are obtained by placing the biometry probe directly on the patient's cornea.

Immersion - In the Immersion technique, an immersion shell containing the probe is placed on the patient's eye and filled with solution between the probe and the cornea (see Figure 3-11). Since the probe is not touching the cornea, there is an offset on the display between the peak from the probe tip and the peak from the cornea.

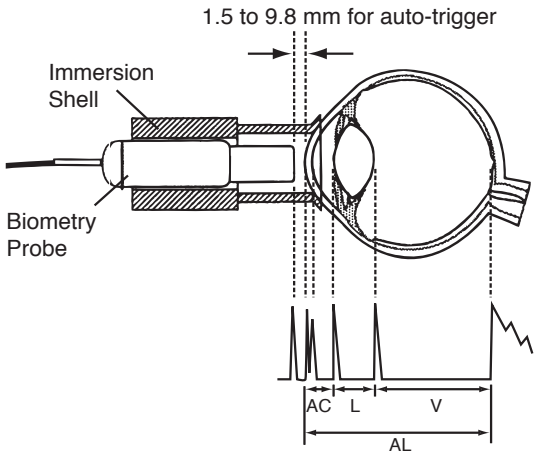


Figure 3-11. IMMERSION TECHNIQUE - The probe tip must be located between 1.5 to 9.8 mm from the cornea in order for the system to automatically lock.

NOTE: In Biometry Immersion mode, the probe tip must be between 1.5 mm and 9.8 mm distant from the cornea in order for the system to automatically lock and freeze.

In Immersion mode the software criteria looks for C1 (anterior cornea) and C2 (posterior cornea). All other criteria for amplitude threshold and peak locations are the same as for the contact modes.

7. Tap the **Volume** drop down menu and select the volume of audible feedback. The selections are OFF, LOW, MEDIUM, and HIGH. The system default is low.

8. Tap the **Gain** field. A window opens that allows you to select a new default Gain setting for that preset. The allowable range is 40-80 dB with a system default of 64 dB.

9. Tap the **Target Ametropia** drop down box. The default for target ametropia is 0.00. The other selections are -0.5, -1.0, and Other. If Other is selected, the acceptable range is -10 to +10.

Phakic Eye Velocities
The Phakic Eye Velocities frame allows you to change the ultrasound velocities for the Anterior Chamber (AC), Lens (L), and Vitreous (V).

10. Tap the **Age Compensation** button to toggle it ON or OFF. If Age compensation is enabled, the software automatically compensates the velocity of the natural lens based on the age entry of the patient. Patient age is entered on the Patient Information screen.

    Age Compensation provides the appropriate ultrasound velocity for the crystalline lens based on age of the patient. Velocity (V) is inversely proportional to the square root of the Density (d) and the Compressibility (c) of the medium. Compressibility is the fractional decrease in volume when pressure is applied to the medium.

$$V = \frac{1}{\sqrt{dc}}$$

    The greater the age of the patient, greater will be the thickness of the lens (greater compressibility and density) and hence lower the ultrasound velocity[1].

11. To change the **AC**, **L**, or **V** velocity, tap inside the field and enter the new velocity in the dialog box. Tap OK to accept the new value. The acceptable velocity ranges are as follows:
    AC: 1400-2000 with factory default at 1532 m/s
    L: 900-2750 with factory default at 1641 m/s
    V: 300-3000 with factory default at 1532 m/s

Acquisition Speed
The Acquisition Speed setting has three selections (Low, Medium, and High) that determine how fast measurements are acquired.

12. Tap the Acquisition drop-down menu and select the desire speed.

Validation
Tapping the Validation Setup button displays the Validation Menu shown in Figure 3-10. The user can activate any of the 12 validation points which will display a message if validation is turned ON and the selected criteria is met. The measurement in question should be repeated and possibly a second person should confirm it. For example: If the first validation point for K < 40 is selected, then a pop-up asking you to confirm the entry will be displayed if a K value less than 40 is entered. To change the criteria for a validation point, simply tap in the field then use the on-screen keyboard to enter the new value. Following is a list of 12 validation points:

- Alerts user that the K value is possibly too low. Default limit is set to 40 D but user can configure as appropriate.
- Alerts user that the K value is possibly too high. Default limit is set to 47 D.
- Alerts user of larger Kavg variance between eyes. Default limit is set to 1 D.

[1] Jack T. Holladay, MD, MSEE, Standardizing Constants For Ultrasonic Biometry, Keratometry And Intraocular Lens Power Calculations. JCRS 1997; 23: 1356-1370

- Alerts user when the Corneal Diameter is possibly too low. Default limit is set to 11 mm.
- Alerts user when the Axial Length (AL) measured is possibly short. Default limit is set to 22 mm.
- Alerts user when the AL measured is possibly long. Default limit is set to 25 mm.
- Alerts user to the possibility of staphyloma when it detects a long eye that either has poor retina peak, standard deviation (SD) is too large, or there is wide variance between the AL of the eyes. Default limit for AL is 26 mm, for SD is 0.10 mm and 0.33 mm for variance. User is advised to perform B-Scan Biometry to confirm.
- Alerts user of larger AL variance between the eyes. Default limit is set to 0.33 mm.
- Alerts user of variability in AL for the same eye. Default limit for SD is set to 0.10 mm.
- Alerts user of a large variance in IOL power between the eyes. Default limit is 1 D.
- Alerts user the possibility of probe not being perpendicular to the eye while some of the measurements were being taken. User may want to retake some of the measurements where some of the peaks are not of similar amplitude.
- Alerts user of possibility of waveform saturation in some of the measurements. User may want to reduce the Gain and retake the measurements that appear questionable.

13. While Validation is ON, tap the Validation Setup button to open the Validation menu. Select the desired options and change any of the values as necessary. Tap Save to save the changes for that Preset (or Esc to exit without saving).

14. Tap the Validation ON/OFF button to toggle the selection for the desired state (ON or OFF).

Audio Feedback

When Audio Feedback is on, the system emits a beeping sound that increases in speed as the quality of the echogram during acquisition improves. Quality of acquisition will improve as all the peaks needed to obtain the axial length increase in amplitude but at the same time are not saturated. Optimum signal condition would result when probe is held perpendicular to the eye with appropriate gain level that does not saturate. Tapping this button toggles Audio Feedback ON or OFF.

Keratometer Index

This entry is used to accommodate the various keratometers that may be used in acquiring the patient's K values. The acceptable range is 1.3315 to 1.3380. The keratometer index should be listed in the keratometer's user manual. To change the value, tap on the screen to display the edit window. This keratometer index entry will only be used for Haigis formula (displayed only when Haigis option is installed). All other formulas expect K values to originate from 1.3375 and therefore the index is fixed at 1.3375 for those formulas.

Sequence
The Sequence section allows you to set the sequence of screens that are displayed when advancing through the biometry screens. The selections that are enabled (blue) will be displayed when the Next screen (Arrow) button is pressed. When all the selected screens have been displayed, the system loops back to the 1st screen. The Patient Information and Scan screens are always enabled.

15. Select or deselect each screen as desired in the Sequence frame.

Pseudo and Phakic IOL Defaults
By selecting a material in the Pseudo or Phakic IOL Defaults list, you can modify the name, velocity, and thickness of the selected material.

16. Select the material to be changed in the Pseudo or Phakic IOL Defaults list, then tap the Edit button.

17. Tap inside the field to be changed, enter the new value, and tap OK to accept the change.

Lens Constants
The Lens Constants screen shown in Figure 3-12 provides the user with the choice of ten IOL's for each setting. The IOL's shown here will be a selection in the IOL Calculation screen (see Figure 3-23) for calculating IOL power. Each entry can be edited to match the user's preferred IOL values. The A0, A1, and A2 entries are used in the optional Haigis formula only and will not be displayed if the Haigis option is not installed. The factory defaults used for A Constant is from the lens manufacturer's specifications.

18. Tap the Lens Constants button. The Lens Constants screen appears as shown in Figure 3-12.

19. Tap one of the rows in the Lens Constants table. The row number appears and fields for all entries can be edited. Press OK to confirm the new values, Esc to return to the Lens Constants screen without saving the changes, or the Trash button to delete an entry.

    All the three constants A, ACD, and SF must be entered when a new IOL is added or modified. Refer to Table 1-5 for IOL constants. The Reset button allows the user to reset the selected row to the factory default IOL and its constants.
    NOTE: If the Haigis option is installed then A0, A1, and A2 will also be reset.

When any of the IOL's in the Lens Constant screen are edited, the designation in the **I/U/C** column changes from **I** (Initial) to **U** (User Change). When constants are calculated using postoperative data in the Lens Constant Update screen, it changes to **C** (Calculated)

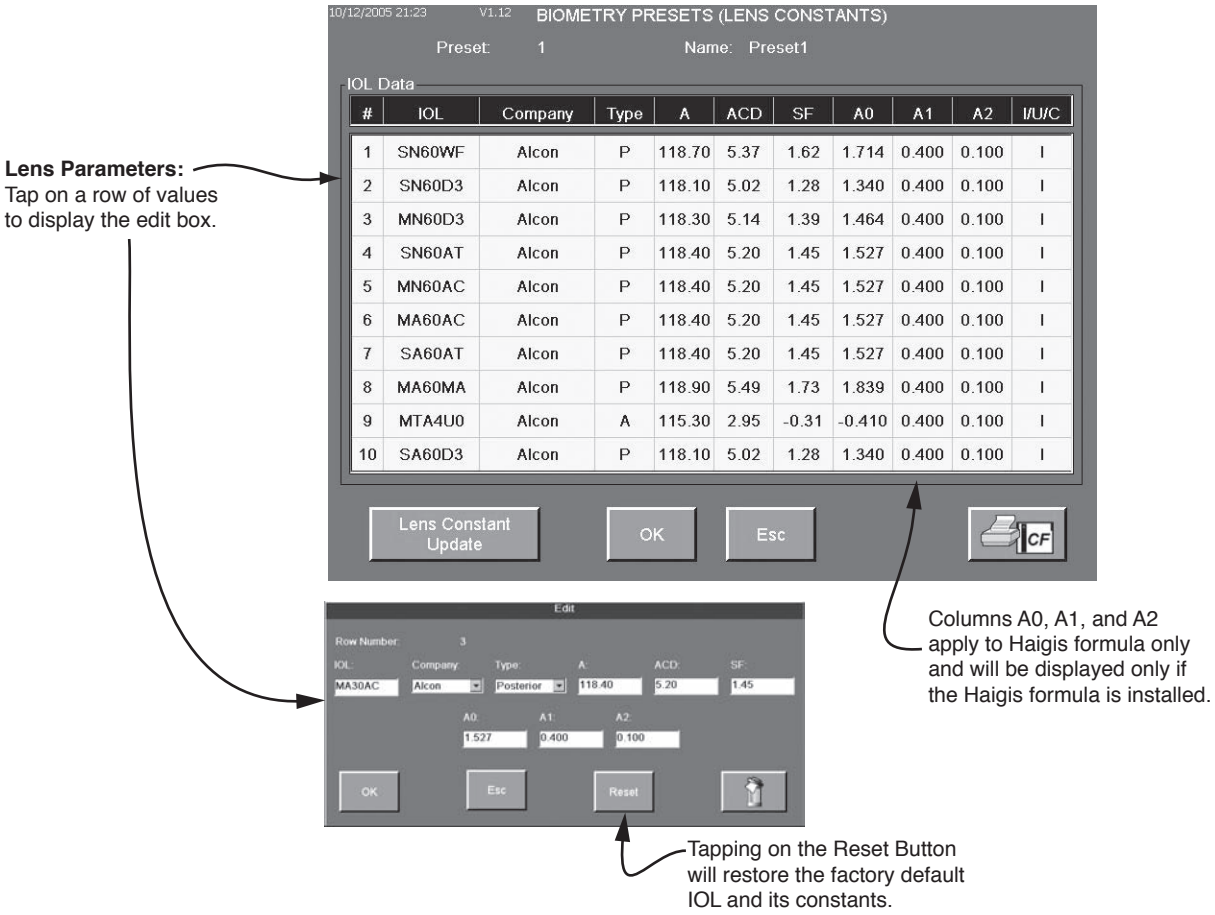


Figure 3-12. LENS CONSTANTS SCREEN - This screen allows the user to make changes to the default values used for the lens constants.

20. Tap the Lens Constant Update button. The Lens Constant Update screen appears as shown in Figure 3-13.

Lens Constant Update Screen

The Lens Constant Update Screen enables the user to customize the A, ACD, and SF constants using the patient's preoperative and postoperative data for any of the ten stored lenses on the selected Doctor Settings Screen. The A constant is used in the SRK-T and SRK-II formulas, SF is used in the Holladay formula, and ACD is used in the Binkhorst-II and Hoffer-Q formulas. Although the system will compute the constants based on a single patient case, a minimum of twenty patient cases should be used in order to achieve higher statistical significance in the prediction of new constants. The system will accept up to fifty patient cases. **NOTE: Use pre-op data for K1, K2, and AL, and post-op data for SPH and CYL.**

The Lens Update Screen displays the name of the lens for which the constants are being changed along with its constants. To select a lens tap the drop down menu beside the lens name, then tap on the desired lens.

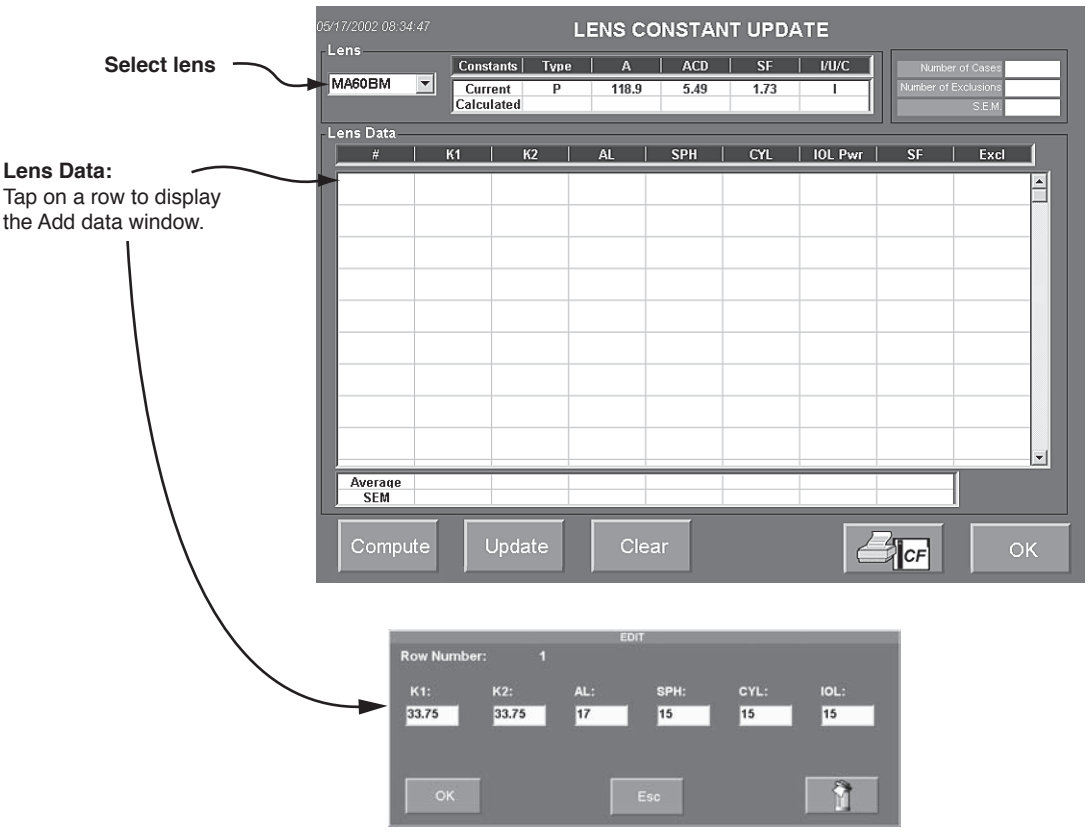


Figure 3-13. LENS CONSTANT UPDATE SCREEN - Lens constants can be updated here based upon actual patient data.

Touching any row of the grid will open the Edit screen or Add screen depending upon whether the row has data to edit or it is a new entry. The following parameter ranges are allowed:

Parameter	Range
K1	28 D (12.05 mm) to 62 D (5.45 mm)
K2	28 D (12.05 mm) to 68 D (4.96 mm)
AL	15 to 39 mm
SPH	-15 to +15 D
CYL	-15 to +15 D
V	0 to 30 mm
IOL	-50 to +50 D

When (SPH + (CYL/2)) < -4, or when (SPH + (CYL/2)) > +4 , the system will require entry of the V (Vertex Distance) parameter, or verification of the default value of V = 12 mm. For each line of IOL implant data that does not require entry of the V parameter, one SF value is automatically calculated. To use the default value of Vertex V=12 mm, press the Enter key. If a new value is desired, delete the default by pressing the Backspace key and typing in the new number.

As data is entered for each case, its SF value is calculated and displayed in the SF column. If SF is less than or equal to 3.10, or more than or equal to 5.10, it is considered as NULL (indicated by the N in the EXCL column) and is excluded from the calculation of the average SF.

After the data entry, the system calculates the following information if the **Compute** button is pressed.

- Average Value (AVR) and Standard Deviation of the Mean (SEM) for each parameter K1, K2, AL, SPH, CYL, and IOL.
- AVR of Surgeon Factor column.
- New calculated constants A and ACD corresponding with calculated SF value. These are displayed below the current constants for the selected lens, and the Identifier I/U/C is changed to C (Calculated).
- Number of cases used for calculations, as well as the number of exclusions and SEM.

  Note: As AVR is calculated, the system excludes the cases in which SF is outside the maximum and minimum ranges, as determined by the formula (SF_{avg} +/- 2*SD). If any cases are excluded for this reason, "X" is displayed in the EXCL column.

The **Update** button updates lens information for the selected lens in the current Preset only and the lens will be labeled as "C" for Calculated. The **Clear** button clears data from the Average and SEM rows. The **OK** button returns the system to the Lens Constants screen.

NOTES:
Do not select the Compute option unless you have actually entered and verified the appropriate values into the LENS UPDATE screen. Before Updating, compare the current constants to the calculated constants to ensure that you want to replace the current constants with the calculated ones. Pressing the Update button will store the new (calculated) constants, and these will be retained under the current Preset.

Consult with the IOL manufacturer if you are in doubt concerning which constant to use in your IOL selection.

21. Return to the Biometry Scan screen by tapping OK at each screen. When OK is pressed at the Biometry Presets screen, you will be prompted to save the new settings for that preset; tap Yes (√) or No (X). **NOTE: Currently unsaved patient data will be lost if the new settings are saved.**

PATIENT SETUP FOR BIOMETRY

Patient information for both Biometry and Pachymetry is entered on the same screen for both procedures if Pachymetry is performed in conjunction with Biometry (user enters via Biometry selection). If user selected Pachymetry from the Menu screen, then a different Patient screen with only Pachymetry related information is displayed (see Pachymetry section).

1. From the Menu screen, tap either the Biometry or Pachymetry button to enter the respective scan screen.

2. Tap the Patient frame as shown in Figure 3-14 to enter the Patient Information screen.

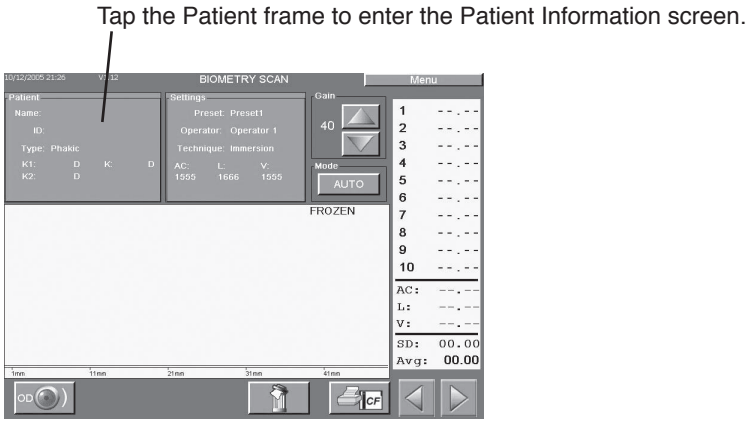


Figure 3-14 THE PATIENT FRAME - Tapping this frame in the Biometry screen opens the patient information screen.

The Patient Information Screen appears as shown in Figure 3-15. If a patient was already displayed on the Biometry Scan screen, the same information will appear on this screen. The current information can be changed or new patients can be entered by tapping the New Patient button which will prompt you to save the current patient (if one was displayed) then clear all the fields for the new data. Previously saved patients can be selected from the patient list by tapping the Patient List button.

When the New Patient button is pressed to enter a new patient, all settings that were changed for the previous patient is returned to the default value. Settings that were changed such as the Gain in the Biometry Scan screen are also returned to the default value.

3. Tap the New Patient button. **NOTE: Always start a new patient by first activating new patient key. Do not manually erase the old patient data and enter new patient.**

4. Tap the Patient Name field. The large field is for the last name (20 character maximum) while the smaller field is for the first name (3 character maximum).

   A keyboard appears (see Figure 2-8) and a dialogue box that allows you to accept or cancel the name entered.

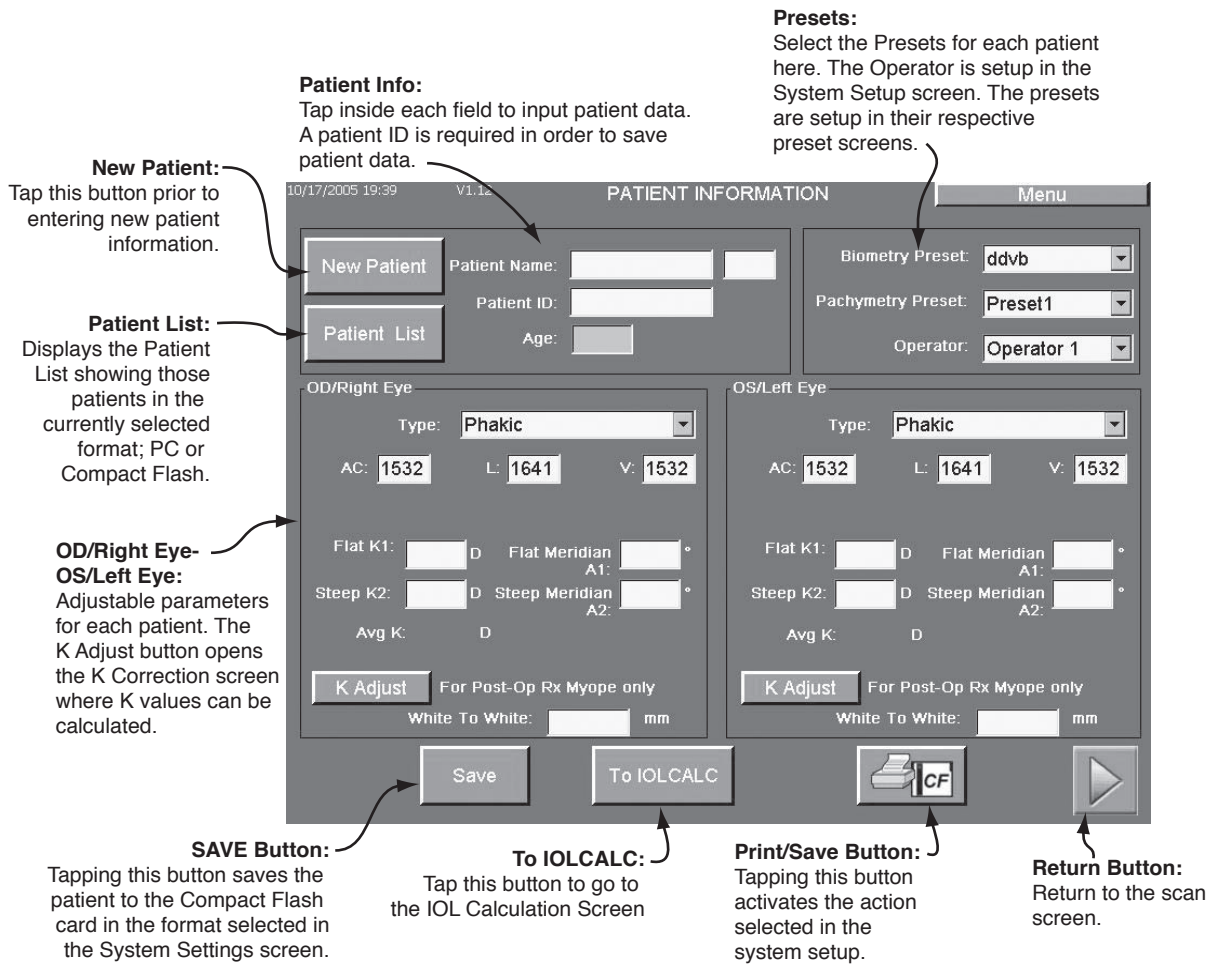


Figure 3-15 THE PATIENT INFORMATION SCREEN- New patients can be entered here or current patient information changed.

5. Enter the last name of the patient by tapping the appropriate letters on the keyboard displayed on the screen then tap OK to accept the name.

6. Repeat steps 4 and 5 for the first name, the Patient ID, and Age fields. If the Age field is grayed-out, Age Compensation is turned off and can be turned on in the Settings screen (see *Setting up the Biometry Presets*).

   NOTE: A Patient ID is required to save patient data since it is used as the filename when saved to the Compact Flash card.

7. Select the desired presets and operator from the respective drop-down menus.

OD/Right Eye and OS/Left Eye
The following parameters are available in the OD/Right Eye and OS/Left Eye frames:

Type - The selections here are Phakic, Aphakic, Pseudo-Phakic, and Phakic IOL. Pseudo-Phakic has several subtypes that include: Pseudo/Acrylic, Pseudo/PMMA, and Pseudo/Custom1-3.

The Phakic IOL selection is used for biometry examinations of patients with IOL implants. Phakic IOL contains several subtypes as follows: Phakic/Acrylic, Phakic/PMMA, and Phakic/Custom4-6.

The Pseudo/Custom and Phakic/Custom selections give the user the ability to enter his commonly used lens such as silicone, etc. The custom parameters must be entered for the lens velocity and center thickness.

AC, L, V - The velocity in meter/sec that the ultrasound passes through the Anterior Chamber (AC), Lens (L), and Vitreous (V). The lens field is not displayed in Aphakic. In the Psuedo-Phakic (L) and Phakic IOL (P) types there is an additional field to input the lens center thickness.

Velocity defaults are provided from the Settings screen but it is possible to change the velocity in the patient screen. For example, the patient may have Silicon oil in the Vitreous. If the velocity is changed for this patient, it will return to the default value when a new patient is entered.

K1 and K2 - Keratometry values are displayed in diopters. The acceptable range for K1 is 28 D (12.05 mm) to 62 D (5.45 mm) while K2 is 28 D (12.05 mm) to 68 D (4.96 mm).

Avg K - The average K reading is displayed in diopters and is automatically recalculated if K1 or K2 changes.

A1 and A2 - Meridian values are displayed in degrees. The acceptable range is 0-360 degrees.

NOTE: Enter flat K and A in K1 and A1 entry fields, and steep K and A in K2 and A2 entry fields, respectively.

K-Adjust (for Post-Op Rx Myope only) - Tapping the K Adjust button opens a dialog box that enables the user to calculate an adjusted K value based on the patient's clinical history. This K adjustment may be necessary for patients who have had Refractive surgery and are now undergoing a Biometry examination.

If Haigis option is installed then KHaigis will be also displayed along with K-Adjust. KHaigis is used for Haigis power calculation.

White To White - This measurement can be made using a commercially available cornea gauge. The acceptable range is 9.0 mm to 15.0 mm. If this measurement is entered in the Patient screen, it will be saved along with rest of the patient information for reference.

8. Select the appropriate setting and values for each eye according to the current patient's condition.

9. Tap the K Adjust button. The Clinical History Method screen appears as shown in Figure 3-16.

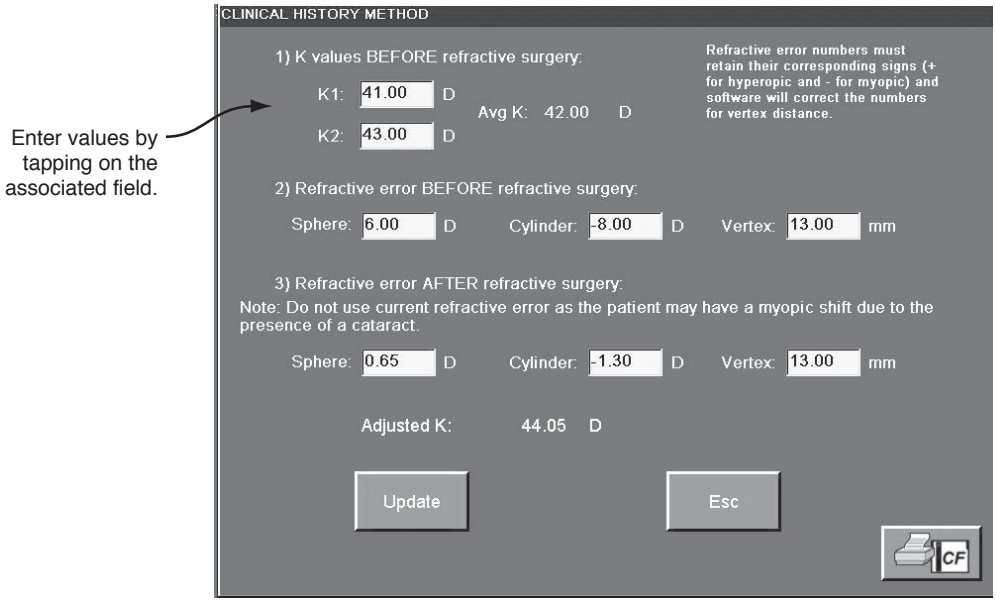


Figure 3-16 THE CLINICAL HISTORY METHOD SCREEN- This is the preferred method for adjusting the K values for patients who have had refractive surgery and have accurate prior records containing the required data.

K values BEFORE refractive surgery:
The acceptable range for K1 is 28 D (12.05 mm) to 62 D (5.45 mm) while K2 is 28 D (12.05 mm) to 68 D (4.96 mm).

Refractive error BEFORE refractive surgery:
Range for Sphere is -15 to +15 D, or corresponding value in mm. Range for Cylinder is -15 to +15 D, or corresponding value in mm. Vertex range is 0 to 30 mm.

Refractive error AFTER refractive surgery:
Range for Sphere is -15 to +15 D, or corresponding value in mm. Range for Cylinder is -15 to +15 D, or corresponding value in mm. Vertex range is 0 to 30 mm.

Adjusted K:
The Adjusted K is automatically calculated after the last value has been entered and then the Update button becomes active. Pressing the Update button will enter the adjusted K value instead of the Avg K value on the main patient information screen.

10. Enter the appropriate values for each field, then press the Update button to transfer the adjusted K value to the patient information screen. Pressing the Esc button returns the system to the patient information screen without changing the Avg K value to Adj K.

11. Once you have returned to the Patient Information screen, tap the Save button to save the changes made to the patient information. Tap the Return arrow to return to the Biometry Scan screen

BIOMETRY SCANS

This section will take you through the process of performing axial length measurements in Manual, Automatic (Auto), and Super-Auto (S-Auto) modes. **NOTE: It is recommended to measure both eyes to compare the measurements and avoid errors.**

1. From the Menu screen, tap the Biometry button and the system will enter the Biometry Scan screen. Figure 3-17 shows a typical screen with callouts describing each section.

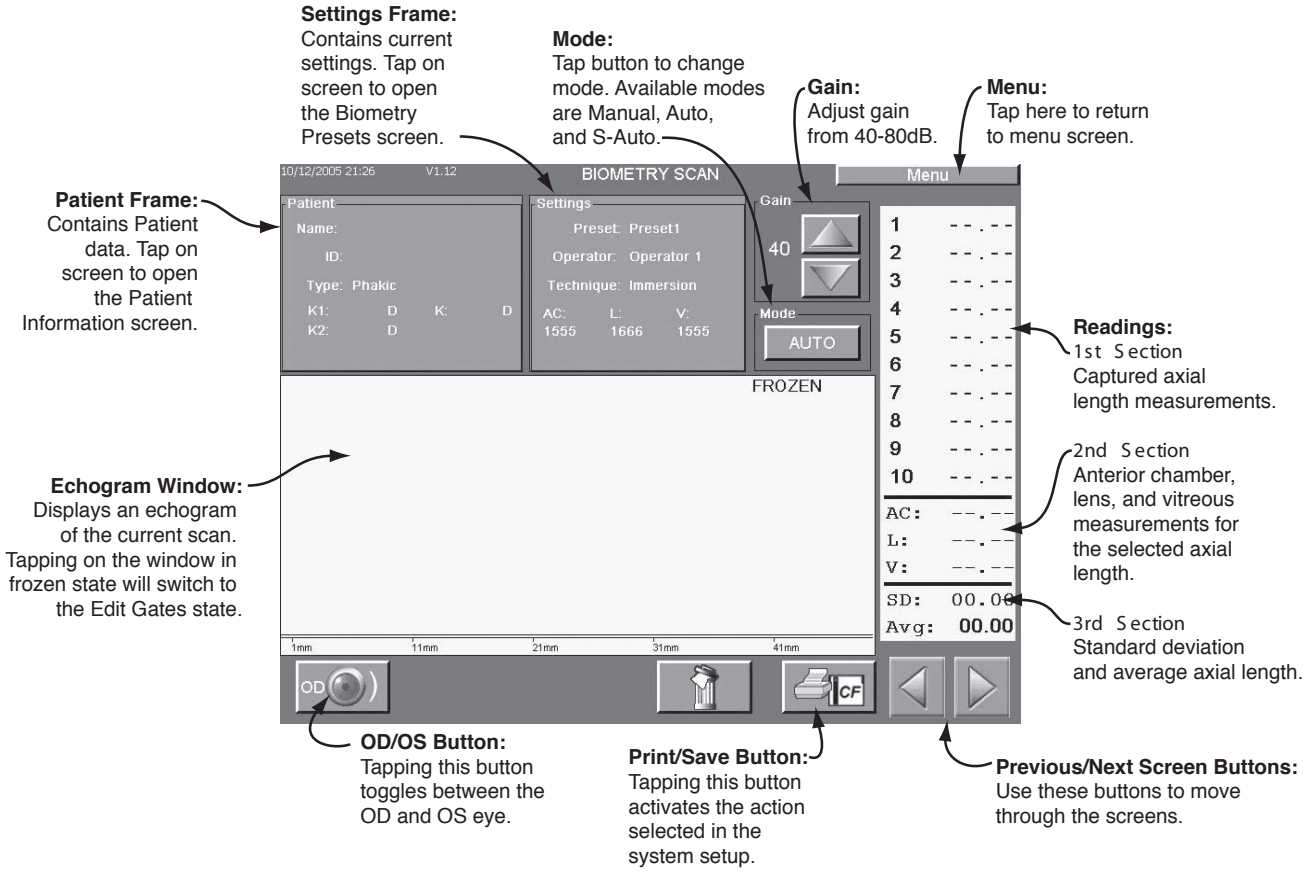


Figure 3-17 THE BIOMETRY SCAN SCREEN - This screen displays the echogram along with measurement readings for each eye. Patient information and settings are displayed and can be changed by tapping on the frame containing the information.

The Biometry scan shows the axial length measurements of the eye. The screen contains fields that display Patient information, the current Settings, Gain adjustment, Mode selection, a graph of the current scan, and the readings. Tapping anywhere inside the various frames and windows on this screen allows you to change settings and data related to that frame.

The Biometry Screen starts in the ***Frozen*** state with the word Frozen being displayed in the Graph window. The system does not emit ultrasound in the *Frozen* state. During the *Frozen* state, the gain can be changed, measurements reviewed, and gates edited.

The user can transition to the ***Running*** state by pressing and releasing the footswitch. During the *Running* state, ultrasound is emitted continuously and the corresponding echogram is shown on the screen.

Biometry Measurements in Manual Mode

In this mode the user unfreezes the system, positions the probe on the eye, and looks for a good waveform (echogram). When a desired waveform is displayed, the footswitch is depressed to save the measurement. Software criteria requires a minimum of cornea and retina peak detection to save the reading.

2. In the Settings frame, ensure that the Contact technique is selected. If not tap the Settings frame and select Contact mode. For further information on technique, refer to *Setting up the Biometry Presets*.

3. Select Manual mode by tapping the Mode button until "Manual" appears on the button.

4. Dip the biometry probe into water and place it on the eye model as shown in Figure 3-18.

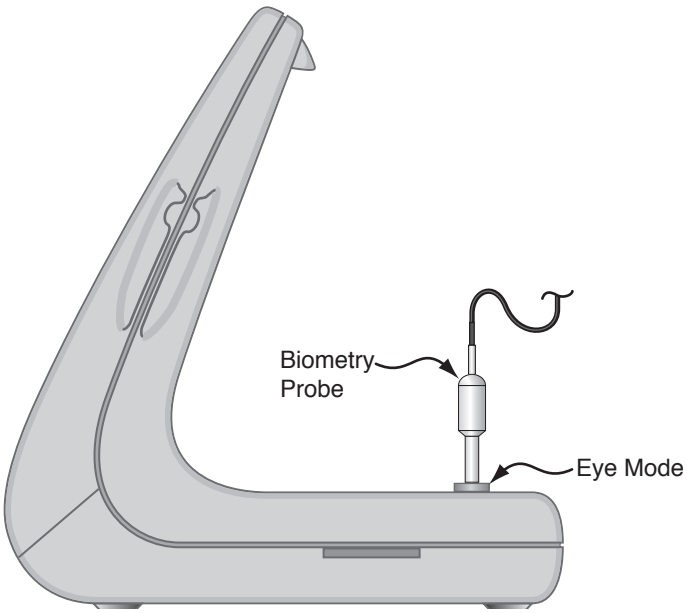


Figure 3-18 USING THE EYE MODEL - Dip the biometry probe into water and place it on the eye model as shown with the probe positioned perpendicular to the base of the system.

5. Press and release the footswitch. The system is now in the *Running* state with the eye model echogram displayed in the graph window. In the Running state, the axial length is displayed in the upper right corner of the echogram and is continuously updated based on the current axial length of the echogram.

   The following actions can be taken in this state:

- Adjust the gain.
- Analyze and save the current reading by pressing and releasing the footswitch within a half-second period. If the footswitch is not released within the half-second period, the system will return to the *Running* state without analyzing and saving the reading.
- Go to the *Frozen* state by tapping the graph window.

6. Adjust the position of the probe and gain until an echogram similar to that shown in Figure 3-19 is displayed, then press and release the footswitch.

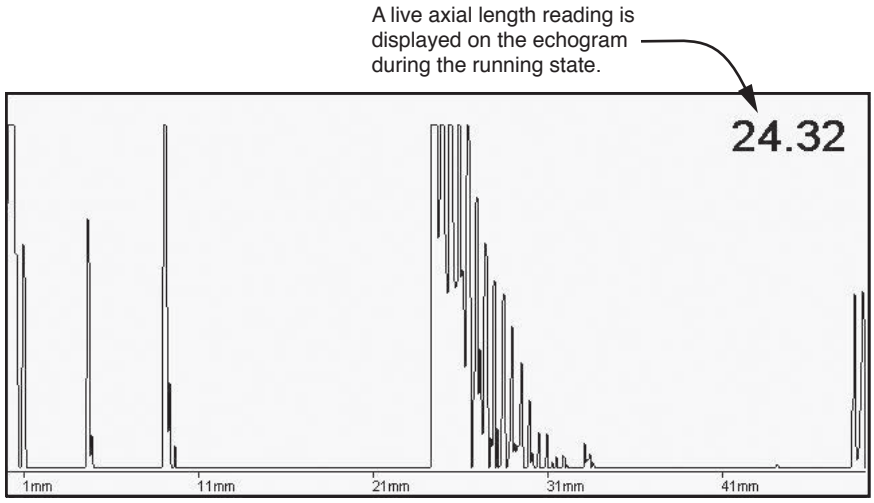


Figure 3-19 DISPLAY OF EYE MODEL ECHOGRAM - Shown here is the echogram during the Running state in Manual mode. Pressing and releasing the footswitch will analyze and save the echogram.

The system records the readings (in Black, Green on Pink color) only if the acquired echogram meets software criteria for peaks in the form of amplitude and ranges. If the echograms do not meet the normal software criteria but are still within the axial length range of 15-39 mm, the readings are displayed in smaller fonts and blue color. The readings with smaller fonts and blue color require in-depth review by the user to ensure validity.

If all peaks were found within the range but some of the amplitudes were lower than normal, then the resultant axial length measurement is displayed in smaller fonts and blue color. If all peaks were not found or if peaks were outside the range then the readings will be displayed as “0.00” and gates will be placed in the default position. If the user reviews the peaks and moves the gates to appropriate locations then the “0.00” will be replaced with the axial length measured.

7. Continue analyzing and saving echograms until all ten positions in the Readings window have data. When all ten positions are full, the system automatically returns to the *Frozen* state and the screen shown in Figure 3-20 appears.

After all 10 readings are taken, the user may review the individual readings using the footswitch. By pressing and releasing the footswitch quickly the user can scroll through the readings. If the footswitch is held for more than 3 seconds, the selected reading will be erased and the system will go into running state to reacquire the deleted reading. The previous steps can be repeated to delete and re-take additional readings.

Selecting a reading from the readings window will display the associated echogram and its AC, L, and V components. The individual gates may be edited by tapping on the echogram window to enter the Edit Gates state.

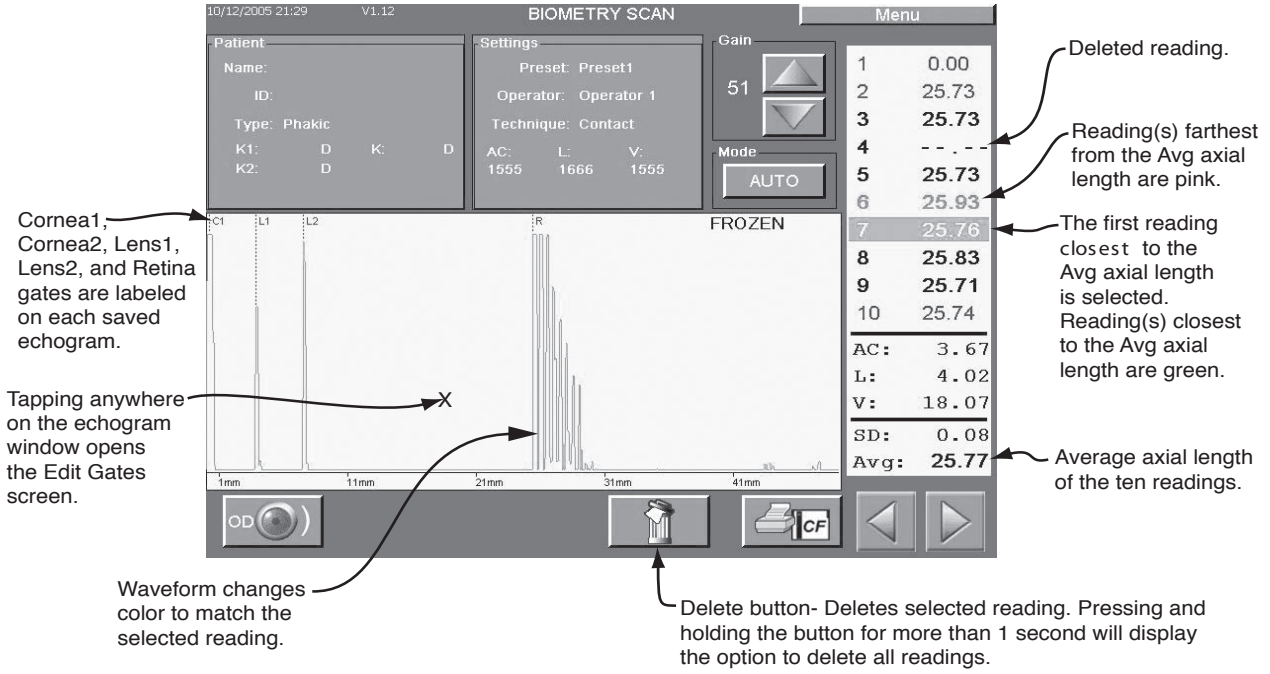


Figure 3-20 BIOMETRY SCAN SCREEN: MANUAL MODE - After analyzing and saving ten echograms, the system automatically selects the scan that is closest to the average axial length.

8. Select a reading from the Readings window by tapping on the reading. The echogram for that reading is displayed in the echogram window.

Editing the Gate Positions

If not all required gates can be determined, then that particular reading will be displayed as 0.00 until the user edits the gates manually. This is accomplished in the Edit Gates state. When each gate is moved, the system automatically recalculates the AL (Axial Length), AC (Anterior Chamber), L (Lens), and V (Vitreous) for this scan. The SD (Standard Deviation) and Avg (Average) values are also recalculated as the new AL is compared to the other nine readings.

9. Tap on the echogram window to enter the Edit Gates state. The system displays the Edit Gates screen as shown in Figure 3-21.

   In Gate Edit mode, no gate is selected until the Gate Select button is pressed. Tapping the Gate select button selects the default gate.

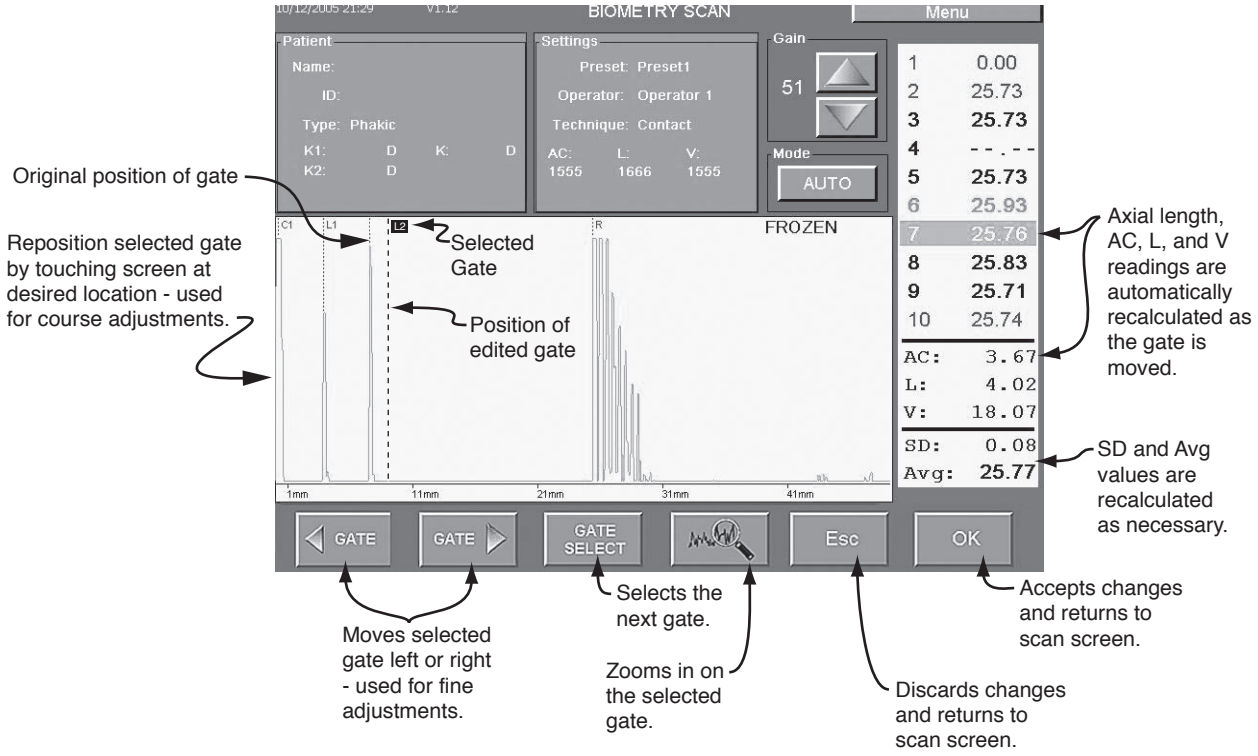


Figure 3-21 EDIT GATES SCREEN - In this screen the selected gate can be repositioned and the associated readings will be automatically recalculated.

10. Select a gate to reposition by tapping the Gate Select button. Tapping the button again moves the selection to the next gate.

11. Reposition the gate by touching the screen at the desired location. The gate instantly moves to the new position and the system displays a vertical line showing the new position of the selected gate as shown in Figure 3-21. Fine adjustments are made using the Gate arrow buttons.

    The echogram may change color depending upon its new relationship to the calculated average (Avg) of all the measurements.
    - Green indicates a measurement that is closest to the average.
    - Pink indicates a measurement that is farthest from the average.
    - Black indicates a measurement in between Green and Pink.
    - Blue indicates a measurement that was acquired using the force freeze function because the waveforms were outside the normal software criteria.

12. Tap the Zoom button. This button enables the user to magnify the selected gate area which is particularly useful when using the arrow buttons for fine adjustments. Tap the Zoom button again to return to the normal view.

13. Press OK to accept the changes or Esc to cancel. The system returns to the normal scan screen in the *Frozen* state.

Biometry Measurements in Automatic (Auto) Mode

14. Select Auto mode by tapping on the Mode button.

15. Press the footswitch and place the Biometry probe on the patient's eye.

    A continuously updating axial length reading is displayed in the upper right corner of the echogram based on the current axial length. For best readings ensure that both the waveform and the axial length number are black as these measurements will automatically save. Blue values must be saved using the force freeze feature by quickly pressing and releasing the footswitch.

16. Adjust the Gain and align the probe to obtain clear and equal amplitudes of C1 and C2 peaks (in immersion mode) along with L1, L2, and a vertical shaped retina peak, then release the footswitch. In Contact mode look for L1, L2, and vertical retina peaks, then release the footswitch.

    The system will take ten measurements if it can lock on the C1, C2, L1, L2 and R peaks. In contact mode C1 is fixed. The echogram auto-lock algorithm is based on amplitude and location of the peaks, and should function adequately for most eyes. In some cases where the amplitude of the peaks are not high enough, or the peaks are not located within the software range, the system may not auto-lock. In these cases, the user may have to use the Forced Freeze Capture option or select Manual mode to obtain measurements.

    The measurements closest to the average are shown in the color green and those farthest away from the average are shown in pink. Measurements in between are shown in black. It is recommended to review the peaks and, if necessary, edit the gates as explained previously in steps 9 through 13. As the gates are adjusted in the Edit Gates mode the readings may change color.

    A single reading can be deleted by touching the reading to select it, then pressing the Delete (trash) button for less than one second. All readings can be deleted by pressing the Delete button for one second. A deleted reading can be refilled by scanning the patient's eye again.

    The *Running* state can be brought into *Frozen* state by tapping on the echogram window. The Running state can be re-entered by pressing and releasing the footswitch.

Forced Freeze Capture:
If it is difficult to take Auto readings, the user can force the capture by pressing and releasing the footswitch within a half-second period. This capture will take place if the system is able to identify at least the cornea and retina peaks and readings will be displayed in smaller fonts and blue color. If all peaks were detected but some have less than normal amplitude, then the measurements will be displayed. If one of the peaks was not found or if peaks were outside the normal software range, then the system will display 0.00 in blue color and gates at default locations until the user manually adjusts the gate locations. The measurements with smaller fonts and blue color require additional review by the user to ensure validity.

Biometry Scans in Super-Automatic (S-Auto) Mode

S-Auto mode is similar to Auto mode except that it automatically adjusts the Gain to get the peaks high enough for auto-lock and at the same time prevents saturation. It also checks that the probe is positioned perpendicular to the eye.

In S-Auto mode, live axial length is not displayed and measurements cannot be captured using the force freeze feature. In addition, S-Auto works only for phakic eyes. If there are problems acquiring measurements in S-Auto mode, then the user should try auto or manual modes.

Biometry Details Screen

17. Press the Next button (right arrow) on the Biometry Scan screen to advance to the next screen selected in the Settings sequence (see *Setting up the Biometry Presets*).

After acquiring eye scans, The Biometry Details screen in Figure 3-22 shows detailed measurement data for all 10 readings of the right and the left eye. The data consists of Axial Length, Anterior Chamber, Lens, and Vitreous. The Average reading and Standard Deviation for each of the above sections is also displayed. If the data does not exist for one of the eyes, then the data for that eye remains blank.

The user may delete unwanted measurements while in the Detail screen. Tapping an entry will select measurements in that row. Pressing the Delete key deletes the entry and the system will automatically recalculate the Average reading and Standard Deviation for that eye. When the measurement is deleted, it is also eliminated from the Biometry Scan screen.

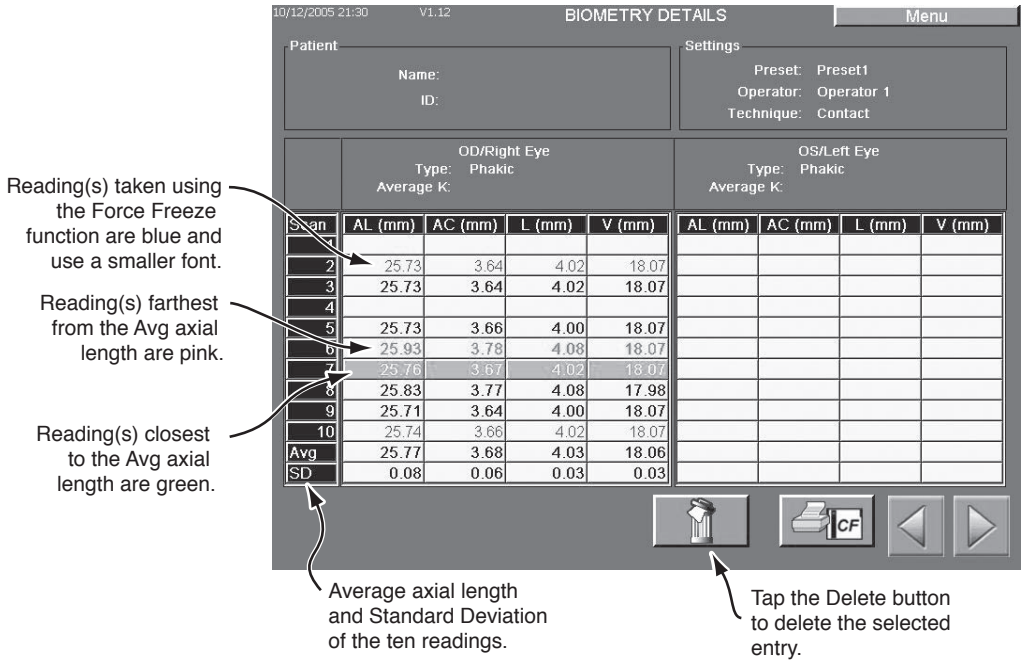


Figure 3-22 BIOMETRY DETAILS SCREEN - This screen shows an overview of up to ten scans each for the right and the left eye. The detail data consists of Axial Length, Anterior Chamber, Lens, and Vitreous; along with the Average reading and Standard Deviation for each of the sections.

IOL Calculation Screen

18. Press the Next button (right arrow) on the Biometry Details screen to advance to the next screen selected in the Settings sequence.

The IOL Calculation screen shown in Figure 3-23 can be used by the operator to perform IOL power calculations using three different user selectable IOL/Formula combinations. The system calculates and displays IOL Power vs. Refraction for each combination. Nine different IOL power calculations that would result in closest refraction around the target ametropia are displayed. The user can then make a choice of IOL power that would be appropriate for the patient.

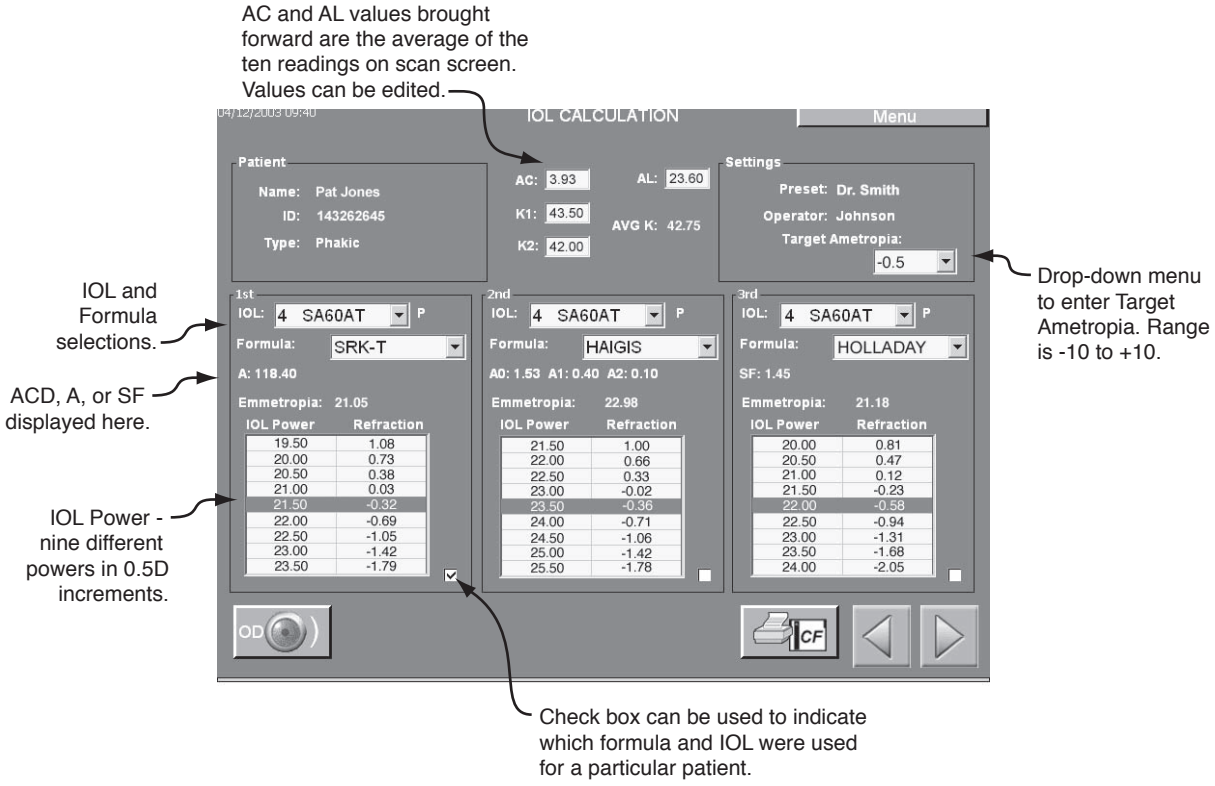


Figure 3-23 IOL CALCULATIONS SCREEN - This screen is used by the operator to perform IOL power calculations.

If K readings were not entered in the Patient Information screen, they must be entered here in order for the system to perform the IOL calculations. For some formulas, an ACD value may also be required. Requirement for calculations to take place is a minimum of one trace reading or average AL entry on the IOL Calculations screen. The AL and AC average values are brought forward from the scan screen. The user may also manually enter the AC and AL values along with K1 and K2 to perform IOL power calculations.

Initially the screen will show factory defaults for lens and formula in each of the three columns. As new selections are made, they will be retained until it is changed again.

19. In the IOL Calculation screen, enter or change measurement information as necessary for AC, AL, K1, K2, and AVG K. Tapping inside each field will open a window that allows new entries. **NOTE: Changing the AC and AL entries will result in the current (unsaved) patient data being overwritten and all measurements for the eye being deleted.**

20. Tap the Target Ametropia drop-down menu and select a value within the range of -10 to +10. The default for target ametropia is 0.00. The user has the choice to type in his own value for any particular patient, but for the next selected patient it will default back to the configuration selected in the Settings screen.

21. Select the desired IOL and formula combinations from the options available in the associated drop-down menus. The ACD, A, or SF for the selected IOL is displayed.

    Using the K value and Axial Length value, the system software calculates and displays lens power and refraction (based on formula, lens selection, and target ametropia). Nine IOL powers are displayed in 0.5D steps that would result in the closest refraction around the target ametropia.

Comparison Screen

22. Tap the Next Screen button (right arrow) on the IOL Calculation screen to advance to the next screen selected in the Settings sequence.

The Comparison screen shown in Figure 3-24 allows the user to compare the IOL power calculations with five different formulas for the three IOL's which were selected on the IOL Calculation screen. The user can select OD/right or OS/left eye. If data does not exist for the eye selected, then the IOL calculations will be blank. IOL power calculations are displayed for both the emmetropia and ametropia.

Formula Configuration Screen

The Comparison screen can be replaced by a Formula Configured IOL Calculation screen where the formula is selected based on length of the eye. In this screen the user selects the eye length ranges and the preferred formula for each range.

23. Tap the Formula Config button.

    The Formula Configuration window is displayed giving the user the option of replacing the default Comparison chart with a set of three IOL calculation charts. These three charts are all calculated using the formula selected for the range that the patient's axial length is within. The fields for axial length are variable within the range of 15 - 39 mm. The default AL values are 22.00 and 24.50. The default formulas are Hoffer Q for the first range, Holladay for the 2nd and SRK-T for 3rd, but the user must accept these formulas or select different ones for those ranges before it is activated.

24. Enter the desired range and select the desired formula for each axial length section then tap OK to go to the Configured IOL Calculation screen.

    The Configured IOL Calculation screen is displayed as shown in Figure 3-24 with a chart for each of the IOL's selected in the IOL calculation screen (see Figure 3-23). The formula used to calculate the charts is listed above along with the basic patient information.

    NOTES:
    After entering the Configured IOL Calculation screen, the system will now use it as the default comparison screen for the current preset. To return to the default Comparison screen, tap the Formula Config button then tap the "X" button in the upper right corner of the dialog box.

    When formula configure is activated it will replace the Comparison screen in the define report window.

25. Tap the right arrow button to advance to the next screen.

26. At the Patient Information screen, save the patient data by tapping on the Save button. If you selected Display Menu in the System Setup screen for the action of the Print/Save button, you can also tap the Records button then tap Save (refer to page 3.6 for detailed information on the Print/Save button).

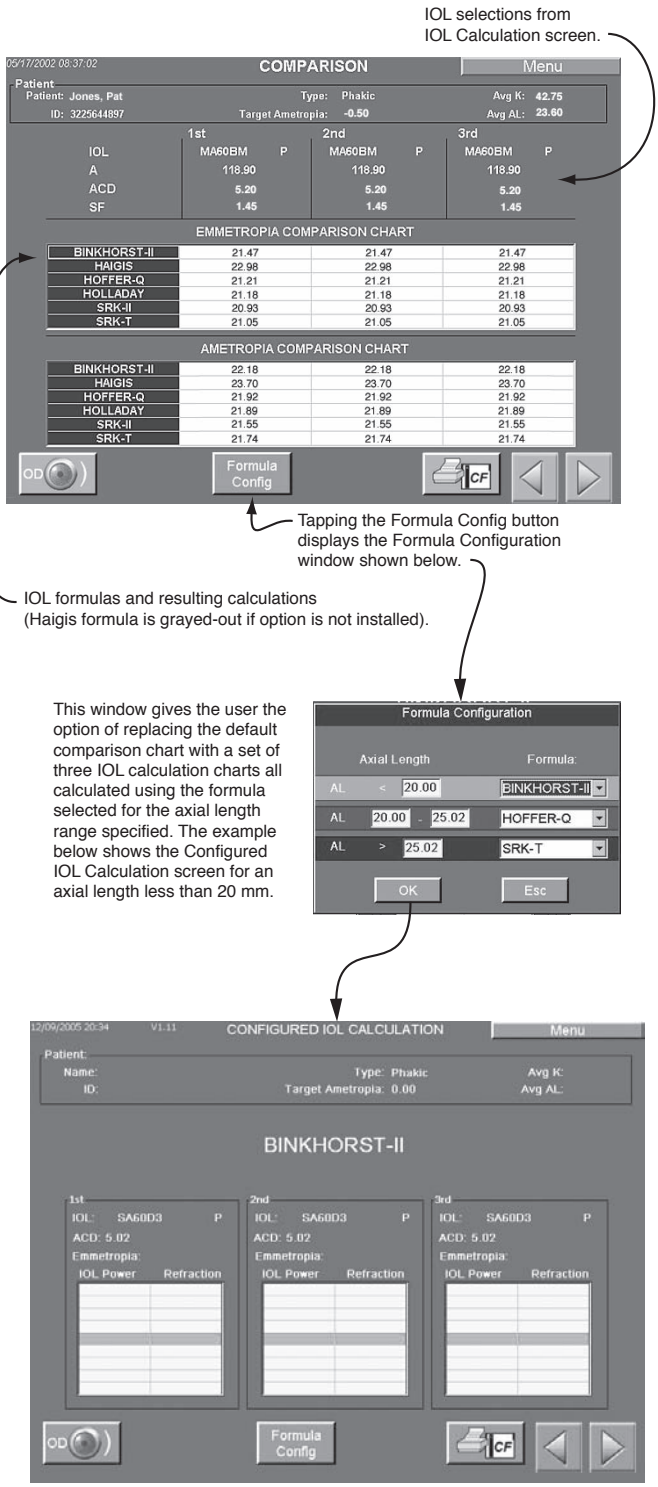


Figure 3-24 COMPARISON SCREEN - This screen shows the calculated IOL power using each of the five formulas for three different lenses that were selected on the IOL Calculations screen. The Configured IOL Calculation screen is available to show calculations using a specified formula for different axial length ranges.

PACHYMETRY

SETTING UP THE PACHYMETRY PRESETS

The system allows the user to set default measurement parameters for up to five preset screens.

1. From the Menu screen, tap the Pachymetry button to enter the Pachymetry Scan screen.

2. Tap the Settings frame. The Pachymetry Presets screen appears as shown in Figure 3-25.

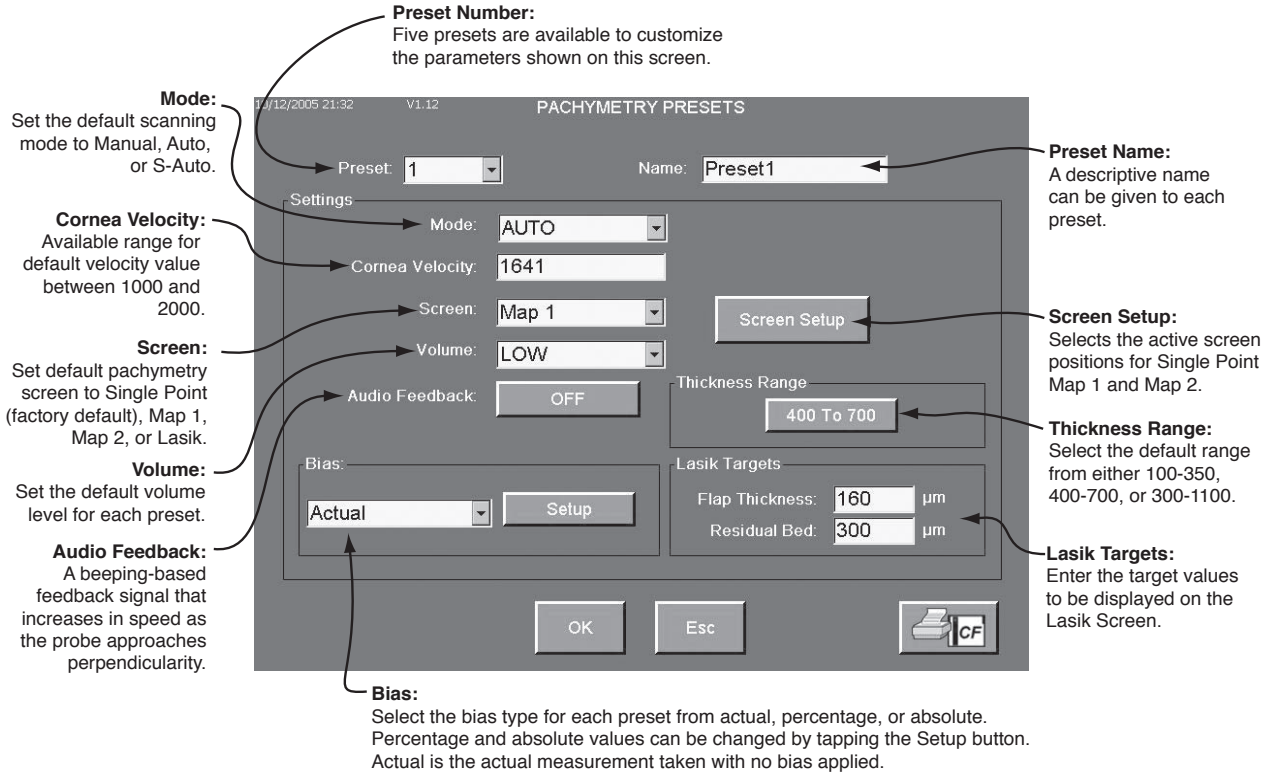


Figure 3-25. PACHYMETRY PRESETS SCREEN - This screen allows the user to configure five different presets.

3. Tap the Preset down arrow to display the drop down menu. Five presets are available and each can be selected by tapping on the number.

4. Tap the Name field. If desired, enter a name for the preset using the keyboard displayed on the screen. Confirm the name by tapping OK.

Settings

The Settings frame contains selections to set the defaults for Mode, Cornea Velocity, Screen layout, Volume, Thickness Range, Bias, and Lasik Targets. Although the Mode, Bias, and Screen can be changed on the Pachymetry Scan screen, the other settings will default to the selection made in this screen and cannot be changed on the scan screen.

5. Tap the **Mode** drop down menu (down arrow) and select the desired mode.

   The Mode setting has three options: Manual, Auto, or S-Auto (Super Auto). The factory default mode is Auto.

   Manual - In this mode, the user presses the footswitch to take a measurement. Then the next position lights up and the current measurement from the probe is displayed. The user must press the footswitch to freeze the measurement and advance to the next position.

   Auto - In Auto mode, the position to be measured starts blinking. When a valid reading has been taken, the system beeps (if audio is enabled), the readings are shown on the position button, and the next position starts blinking. If the footswitch is pressed, the position backs up and erases the last measured value.

   S-Auto - Super Auto mode is similar to Auto mode except that a minimum of three valid readings are taken and the shortest reading is displayed. Each reading is accompanied by voice confirmation of the measurement.

   In all modes the user can set the next position manually by pressing a position on the screen.

6. Tap the **Cornea Velocity** field, input the new value, and press OK to accept the change. The acceptable range is between 1000-2000 m/s with a factory default of 1641 m/s.

7. Tap the **Screen** drop-down menu and select the default screen that will appear when entering Pachymetry mode. There are four selections available: Single Point Map 1, Map 2, and Lasik.

The Single-Point Screen

In this screen a sequence of up to ten numbered positions is displayed allowing the user to take repeated measurements of a single point on the cornea. The number of points is set by the user in the Pachymetry Settings screen.

Map 1/Map 2

Selecting Map 1 or 2 activates the Screen Setup button which, when pressed, will display the Screen Setup for the selected Map (see Figure 3-26). In the Screen Setup you can select which of the 25 available positions will be displayed on the Pachymetry Scan screen for each preset. Tapping on a position toggles it between selected or unselected. When selected, a number appears indicating the position is active and its order in the scanning sequence. Pressing the delete button will clear all positions to the unselected state.

There are two ways to configure the Maps.

- Using the default map provided, tap on the position buttons that you want to disable. In this case the sequence will stay the same.
- Delete all the buttons by pressing the delete button. Then touch each button that you want to activate in the sequence that you want to take the measurements.

The Lasik Screen

The Lasik Screen is designed to acquire data during the four main phases of a Lasik procedure: Preoperative, Post-Flap, Post-Ablation, and Post-Op.

8. Select Map 1, then tap the Screen Setup button. The Screen Setup appears as shown in Figure 3-26.

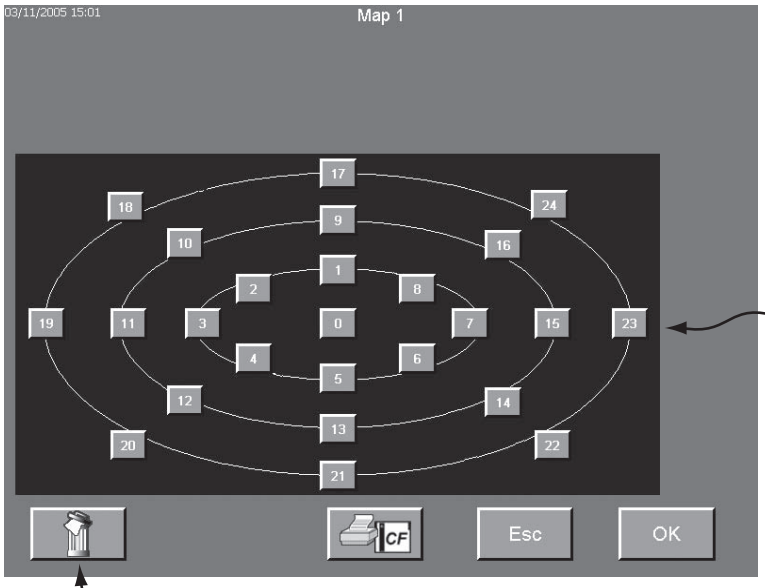


Figure 3-26. PACHYMETRY SCREEN SETUP - This screen allows the user to configure which positions will be active during acquisition.

Individual buttons may be deleted (set inactive) from an existing map. When a button is deleted, the remaining buttons are reordered so that the numbers show the new scanning sequence.

9. Press the Delete button to clear the current button positions.

10. Select the buttons that you want available during acquisition in the desired sequence. As each button is selected a number appears indicating it is active and its order in the scanning sequence.

11. Press OK to save the changes if desired.

12. Tap the **Volume** drop-down menu and select the default volume level for this preset.

13. Tap the Audio Feedback button to toggle the feature ON or OFF.

    Audio Feedback is a beep-based feedback signal that increases in speed as the probe approaches perpendicularity.

14. Tap the **Thickness Range** button to set the default range. The three choices are: "100 to 350", "400 to 700", or "300 to 1100" in μm. The selection made here will be displayed as the default on the Pachymetry Scan screen.

15. Tap the **Bias** drop-down menu and select the default bias type for this preset.

    There are three options available: actual (no bias applied), percentage, and absolute. Percentage (range = 0 to 300%) and absolute bias (range = -999 to 999 μm) values can be changed by tapping the setup button and entering the desired value.

    Biasing corneal thickness means either subtracting or adding a number from the actual thickness of the cornea. This function is normally used by refractive surgeons prior to surgery to visualize post-op corneal thickness and to plan for the surgery. As an example, for a 640 micron corneal thickness, 10% Bias will display as 64 microns, -10 μm Bias will display as 630 microns, and 20 μm Bias will display as 660 microns.

16. Enter the desired values for **Flap Thickness** (range = 70 to 200 μm) and **Residual Bed** (range = 200 to 400 μm) by tapping inside the respective field in the Lasik Targets frame.

17. Tap the OK button to return to the Pachymetry scan screen. When prompted to save the preset, tap Yes (√) or No (X).

PACHYMETRY SCANS

The Pachymetry Map screens allow the user to acquire corneal thickness measurements on either eye. There are four different types of screens available to perform measurements and save data in the format needed for each specific patient. The available screens are:

- **Single Point** - This screen is intended to allow repeated measurements of a single point on the cornea and save them as a sequence of up to ten numbered positions on the screen per eye.
- **Maps 1 and 2** - Each screen has up to 25 programmable locations positioned in the general topography of the eye. **Note: Only one of these screens can be used for a particular patient.**
- **Lasik** - This screen allows the user to acquire and save data in a format showing measurements in the four main phases of the Lasik procedure: preoperative, post-flap, post ablation, and postoperative.

1. From the Menu screen, tap the Pachymetry button. One of the four pachymetry screens appears depending upon the default selection in the Pachymetry Presets. The factory default is Single Point as shown in Figure 3-28.

Pachymetry Patient Setup

If Pachymetry is performed in conjunction with Biometry (user entered by selecting Biometry from Main menu) then Patient information for both Biometry and Pachymetry is entered on the same screen for both procedures as described in *Patient Setup for Biometry* earlier in this section. If Pachymetry was entered by tapping the Pachymetry button on the Menu screen, then patient data is entered as described in step 2.

2. Tap the Patient field (see Figure 3-28) to enter the Patient Information screen as shown in Figure 3-27. Enter the desired information then press OK to return to the Pachymetry scan screen.

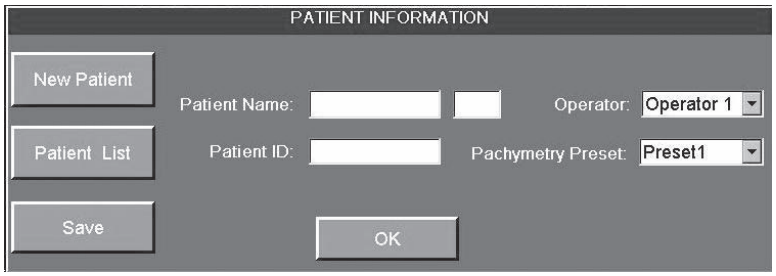


Figure 3-27 PACHYMETRY PATIENT INFORMATION SCREEN - Patient information for patients requiring pachymetry measurements only are entered in this screen.

3. Tap the Single Point button to advance to Map 1.

4. Tap the Map 1 button to advance to Map 2. Map 2 is the same as Map 1 except that the scan locations may be configured differently.

5. Tap the Map 2 button to advance to the Lasik screen. The Lasik screen appears as shown in Figure 3-30. It is customized to meet the needs of Lasik surgery with readings arranged for Pre-Op, Post-Flap, Post Ablation, and Post-Op.

6. Tap the Lasik button to return to the Single Point screen.

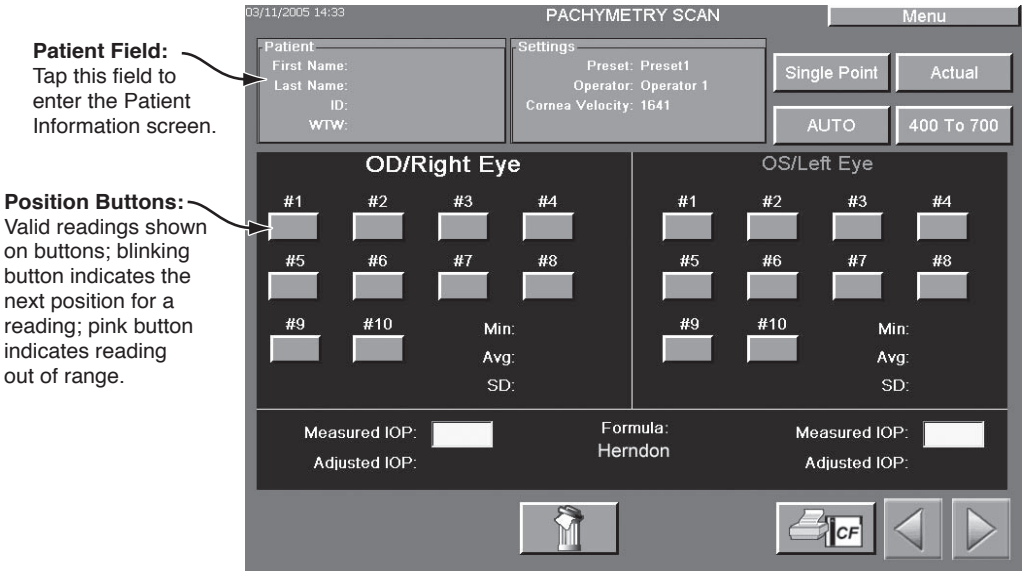


Figure 3-28 PACHYMETRY SINGLE POINT SCREEN - The Single Point screen allows the user to record multiple scans of a single point on the cornea.

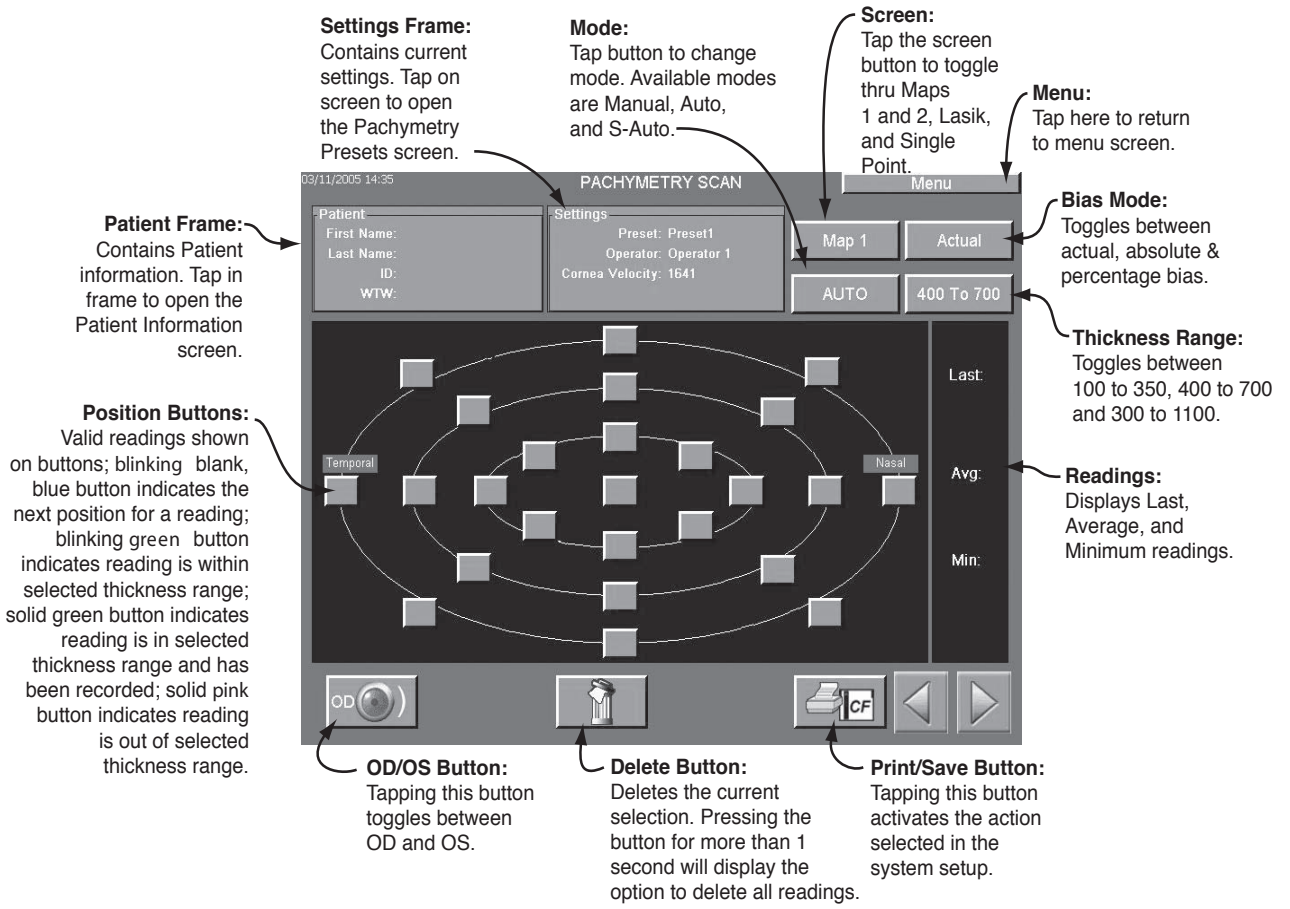


Figure 3-29 PACHYMETRY MAP 1 or 2 - Maps 1 and 2 can be configured with up to 25 locations for taking corneal thickness measurements.

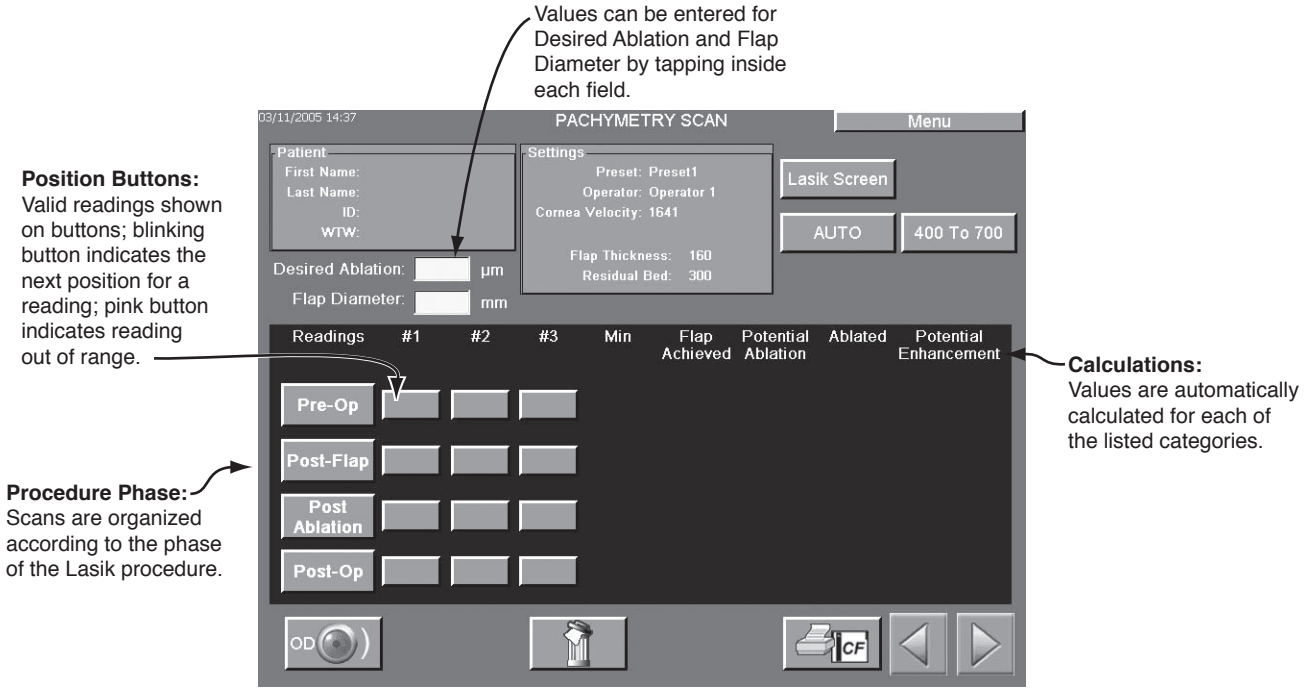


Figure 3-30 PACHYMETRY LASIK SCREEN - The Lasik screen allows the user to organize scans by the four main phases of Lasik surgery.

Pachymetry Scans in Manual Mode

In Manual mode the user presses the footswitch to save each measurement. The current position blinks indicating the location where the measurement will be saved.

7. Ensure that the Pachymetry probe is connected to the rear panel and the Mode button displays **Manual**.

8. Set the **Bias** and **Thickness Range** buttons to the desired values.

   The **Bias** button allows you to toggle between actual measurements, absolute bias (-999 to 999 μm), and percentage bias (0 - 300%). The values used for absolute and percentage bias are entered in the Settings screen.

   The **Thickness Range** determines the range that a reading must fall within to be valid. The three thickness ranges to select from: 100 to 350 μm, 400 to 700 μm, or 300 to 1100 μm.

9. Tap any scan # on the Single Point screen. The position starts blinking.

   When the system receives a measurement within the range shown on the Thickness Range button, the position turns green and the measurement is displayed but will remain blinking until the footswitch is pressed and released to capture the measurement. If the measurement is outside the selected thickness range, the position will turn pink.

10. Place the pachymetry probe on the patient's eye.

11. When a valid measurement is displayed on the blinking position button, press and release the footswitch to capture the measurement. The measurement is displayed on the scan # button, which will turn light green if the measurement is within the selected thickness range or pink if the measurement is out of the thickness range.

    The next position button in the sequence will start blinking as it waits for another measurement. If a measurement must be retaken in a position, tap the button and it will delete the old measurement, then a new measurement may be taken to replace it.

Pachymetry Scans in Auto Mode

In Auto Mode the system automatically captures a reading when a valid measurement is detected.

12. Tap the Mode button to switch to Auto mode.

13. Tap any position button on the screen. The position starts blinking.

14. Place the probe on the patient's cornea. The system automatically captures a reading when a valid measurement is detected, then advances to the next position and blinks.

Pachymetry Scans in S-Auto Mode

Super Auto mode is the same as Auto mode except that a minimum of three valid readings are taken and the smallest measurement is recorded. The smallest measurement indicates that the probe is perpendicular to the cornea. If the sound setting is enabled, a voice confirmation of the reading is announced.

For Maps 1 and 2, the user can go back and retake the previous reading by pressing the footswitch.

Pachymetry Scans using the Single Point Screen

In Single Point screen the eye selected is highlighted either OD or OS. After all the configured measurements are taken for an eye, you can select a point and delete as needed. Pressing the footswitch and releasing in less than 1 second will make the last reading blink.

In Auto, repeatedly pressing the footswitch will scroll through each scan # causing each one to blink. If the footswitch is not pressed within 4 seconds to move to the previous location, then it turns pink indicating that the reading was deleted and a new reading must be taken for that scan #. If the footswitch is pressed within the 4 seconds, the blinking moves to the previous location without becoming pink. This selection cycle goes in reverse order through the readings.

After all configured (up to 10) readings are taken for the selected eye, you can switch to the other eye by tapping OD/Right Eye (or OS Left Eye) or pressing and holding the footswitch for 5 seconds. To begin the measurement, press and release the footswitch or tap the scan #1 and it will blink indicating it is ready.

IOP

IOP Adjustment is displayed only when the selection is Actual. The user enters measured IOP and, based on the average CCT value, the system will calculate and display Adjusted IOP. The formula used for CCT based adjustment is based on a conversion table developed by Dr. Leon Herndon, MD and assistant professor at Duke University Medical Center. Dr. Herndon's table is a modified version of original conversion factors developed by Dr. N. Ehlers[1].

[1] Leon Herndon, MD, Rethinking Pachymetry and Intraocular Pressure, Durham, N.C. Review of Ophthalmology July 2002

Pachymetry Scans using the Map Screens

The Map Screen shown in Figure 3-29 enables the user to take measurements in up to 25 programmable locations positioned in the general topography of the eye. **Note: Only one of these screens can be used for a particular patient.**

Begin taking measurements by tapping a position button on the screen. The Manual, Auto, and S-Auto modes function the same as in Single Point mode. In all modes, the next position can be set manually by tapping the next position on the screen.

Pachymetry Scans using the Lasik Screen

To begin capturing measurements in the Lasik Screen (Figure 3-30), the user selects one of the four Lasik phases then selects a position in that row. Once scanning begins, the system keeps scanning until three valid measurements have been taken. The system records the smallest (minimum) of the three measurements. The Manual, Auto, and S-Auto modes function the same as in Maps 1 and 2.

Values for Desired Ablation and Flap Diameter can be entered for reference by tapping in the associated field.

The five columns to the right of the readings are used as follows:
Min = minimum reading for each phase.

Flap Achieved = (Pre-Op Minimum) - (Post-Flap Minimum)

Potential Ablation = (Post-Flap Minimum) - (Target Residual Bed)

Ablated = (Post-Flap Minimum) - (Post Ablation Minimum)

Potential Enhancement = (Post-Op Minimum) - (Flap Achieved) - (Target Residual Bed)

COPYING PATIENT DATA TO A PERSONAL COMPUTER

CAUTION

The patient data stored on any device other than the *OcuScan®* RxP is not validated by Alcon, therefore it can be used for reference only. The data stored on other devices such as a PC should never be used for diagnosis or calculation of IOL power. IOL calculations should be performed using the *OcuScan®* RxP system only.

Patient data can be copied to a personal computer (PC) for backing up and viewing using the Patient Viewer. The Patient Viewer is a template that is named PatientViewer.exe. It is contained on the CD-ROM that is shipped with the system.

Requirements for viewing data on a PC:

- Original files on the *OcuScan®* RxP must be saved in the PC format. In System Setup screen, confirm that PC Format is selected in the Save Patient Format field.
- PC System running on Windows 98, ME, 2000, or XP. **NOTE: Older versions of Windows may require a service pack upgrade.**
- Create a folder on the PC for storing the patient files. Assign a relevant name to the folder such as "Patient Files."
- Microsoft .Net Framework must be installed in the PC prior to running the Patient Viewer. The Patient Viewer will NOT function properly without this update. This program may be downloaded via the internet at: http://msdn.microsoft.com/netframework/downloads/

    1 While in the download screen Left Click on "SDKs, Redistributables & Service Packs" from the choices presented in the center of the screen.
    2 Next Left Click on the latest version of the .Net Framework (i.e. .NET Framework Version 2.0 Redistributable Package (x86)) displayed on the screen.
    3 Then Left Click on the Download button located on the top right hand side of the screen.
    4 Follow Microsoft's steps to Save it on your PC and then run the .exe file that was downloaded.
    5 Follow the screen prompts.

- Copy the "PatientViewer.exe" and ZedGraph.dll file from the OcuScan® RxP CD-ROM to the PC, preferably in the folder where the patient files are stored.

There are three ways of transferring patient data to a personal computer (PC):

- Using a Compact Flash card reader connected to the PC.
- Connecting the *OcuScan®* RxP Measuring System directly to a PC through the USB port.
- Connecting the *OcuScan®* RxP Measuring System to a local network through the ethernet port.

Using a Compact Flash Card Reader to Transfer Patient Data

1. Connect a Compact Flash card reader to your PC. If your computer is not already equipped with the card reader, you may purchase one at a computer store. Since most of these readers use a USB connection, your PC must be equipped with a USB port.

2. Remove the Compact Flash card from the *OcuScan®* RxP Measuring System and insert it into the card reader connected to the PC. The Compact Flash card should automatically mount and be accessible through "My Computer" or Windows Explorer.

3. Copy the patient files from the Compact Flash card to the folder (Patient Files) you created on the PC hard drive. Patient files are assigned names from the patient ID numbers entered on the *OcuScan®* RxP.

Transferring Patient Data to a PC through a USB Connection

Hardware Requirements: available USB port on PC and an A to B USB cable.

1. Install the USB driver.
   1.1 Place the CD-ROM provided with the *OcuScan®* RxP Measuring System into the CD drive on the PC.
   1.2 Copy the following files to a location on the PC: Wceusbsh.inf and Wceusbsh.sys.
   1.3 Start up the *OcuScan®* RxP Measuring System and allow it to boot up.
   1.4 Connect a USB cable between the PC and the *OcuScan®* RxP Measuring System.
   1.5 When prompted at the "Add New Hardware" screen, follow the prompt and locate the driver (Wceusbsh.inf) in the location it was copied to in step 1.2. Follow the directions displayed on the screen.

2. Install the *Microsoft ActiveSync* application.
   This application can be downloaded via the internet at:
   http://www.microsoft.com/mobile/pocketpc/downloads/
   Select on the latest version of ActiveSync from Microsoft Downloads. After downloading, follow the installation instructions.

3. Connecting to the PC.
   3.1 Power-up *OcuScan®* RxP Measuring System and allow it to boot-up.
   3.2 After boot-up, connect the USB cable from the PC to *OcuScan®* RxP Measuring System.
   Note: Older versions of ActiveSnyc require the USB cable to be disconnected and reconnected every time the PC is shut down.

   On the *OcuScan®* RxP Measuring System, a dialog box will appear reporting that it is trying to connect to the host. Do not click on any buttons.

   On the PC, *ActiveSync* will appear reporting the connection and ask if you want to set up a partnership - click "No" then the "Next" button (see Figure 3-31).

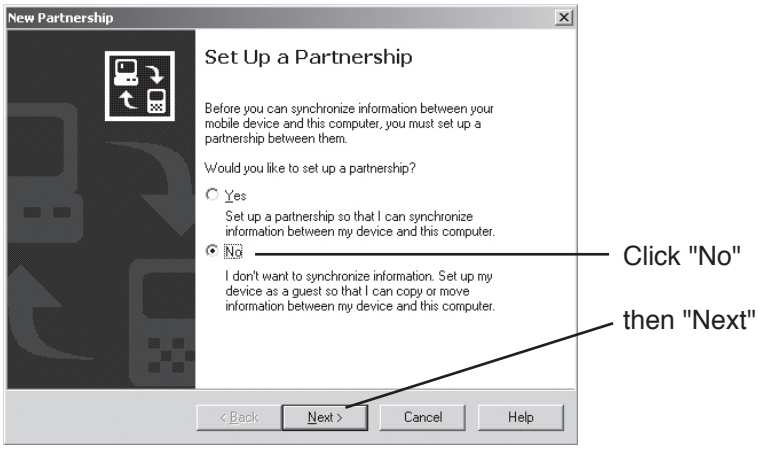


Figure 3-31 The ActiveSync Partnership Screen - This screen appears on the PC prior to synchronization with the *OcuScan®* RxP Measuring System.

4. In the *ActiveSync* window, click the Explore button, locate the Patient data files and copy them to the Patient Files folder on the PC. Figure 3-32 shows the sequence of screens you will go through to complete this step.

5. Select the required patient files (.csv), then drag and drop them from the storage card to the folder created on the PC (Patient_Files).

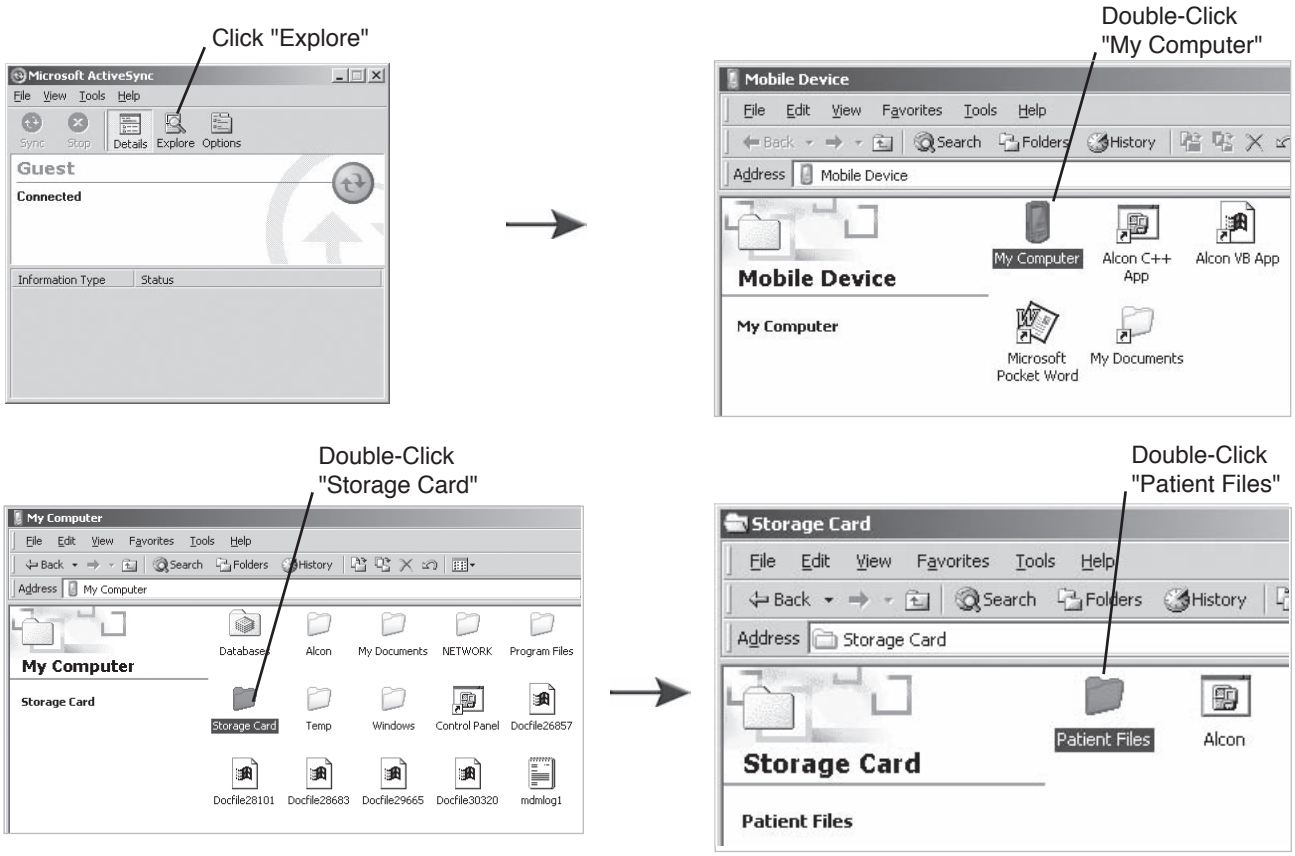


Figure 3-32 Accessing Patient Files through a USB Connection - This sequence of screens shows how to copy patient files to the PC.

Transferring Patient Data to a PC through an Ethernet Network Connection

1. Working with your network administrator, connect the *OcuScan*® RxP Measuring System to the local network through the ethernet port on the rear panel. The device is configured as a DHCP client by default, therefore it will automatically request an IP address from a DHCP server on the network.

   Note: If connecting to a static network please contact Technical Support for help on reconfiguring the *OcuScan*® RxP.

2. Launch a browser program (such as Internet Explorer) on a PC connected to the same network.

3. Access the *OcuScan*® RxP Measuring System by using the device name in the Address line of the browser as follows: **http://NGO/patientfiles** (see Figure 3-33).
   NOTE: If the device name was changed from NGO (default), use the newly configured name.

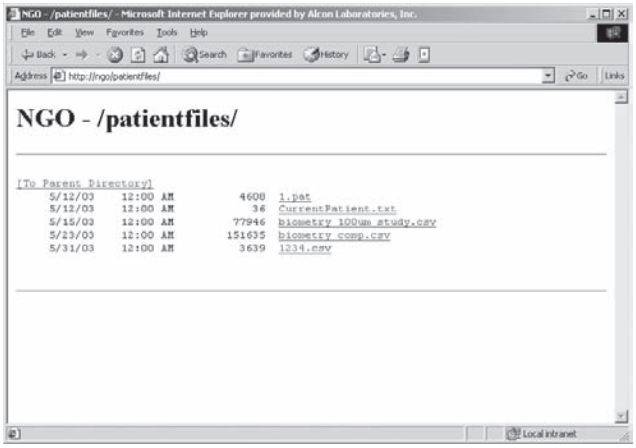


Figure 3-33 ACCESSING PATIENT FILES THROUGH A NETWORK - Internet Explorer browser screen displaying the patient files on the *OcuScan®* RxP Measuring System.

4. Right click on the patient file(s) to transfer and select "Save Target As." Select the Patient files folder that was created (see Figure 3-34).

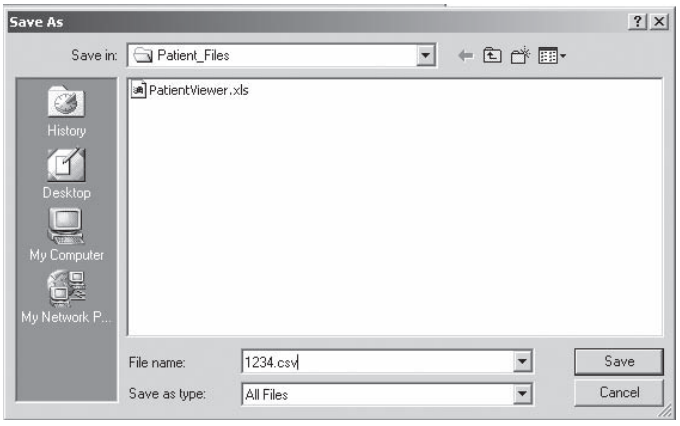


Figure 3-34 SAVING PATIENT FILES TO THE PC.

5. Select "All Files" from the "Save as type" pull down menu, and change the patient file extension from .htm to .csv in the "File name" box.

Viewing Patient Data on a PC

Patient data files that are saved in the PC Format and copied to a PC can be viewed using the Patient viewer template.

1. Open the Patient Viewer by double clicking the “PatientViewer.exe” file. The patient viewer will appear as shown in Figure 3-35.

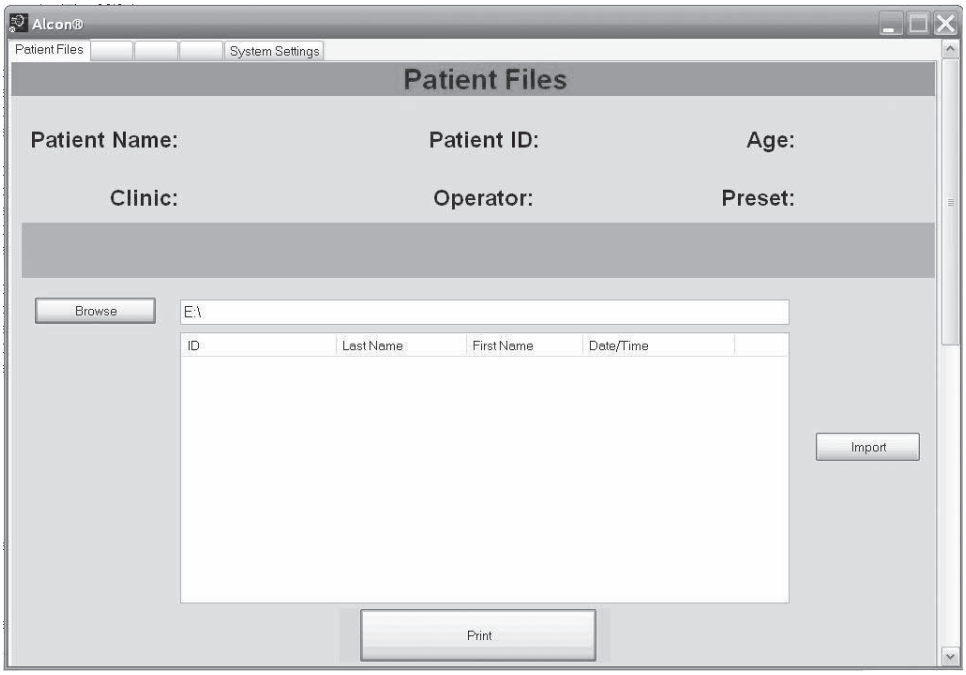


Figure 3-35 THE PATIENT VIEWER - This illustration shows the opening screen of the Patient Viewer.

2. Click on the browse button and navigate to the location where the folder containing all patient files saved in PC format.

3. Click on the folder and select the “OK” button.

4. The patient data files are now displayed in the middle of the screen as shown in Figure 3-36. Each file shows the patient ID, Last Name, First Name and the Date/Time the file was last modified.

Figure 3-36 PATIENT VIEWER WITH PATIENT DATA - This screen shows the opening screen of the Patient Viewer after loading patient data.

NOTE: The type of sorting used to organize the patient files depends upon whether the PC uses an NTFS or FAT file system. An NTFS system sorts alphanumerically, while FAT sorts in the order the files are saved. To determine which file system is used on your PC hard drive, right click on the drive icon then select Properties. The file system type is displayed under the General tab.

5. Click on the Patient ID number you want displayed, then click the Import Button.

6. Click on the System Settings tab near the top of the window to view the language selection and to define the print options for the biometry and pachymetry screens, as shown in Figure 3-37. The settings for language selection and print are saved until changed again.

   The Language box allows the user to choose from English, Francais, Deutsch, Italiano, Japanese, Protugues, and Español.

   The Define Print box allows the user to choose to print Biometry, Pachymetry or both. After the selection has been made click on the “Print” button. (The user may also print by pressing the Print button at the bottom of each page.)

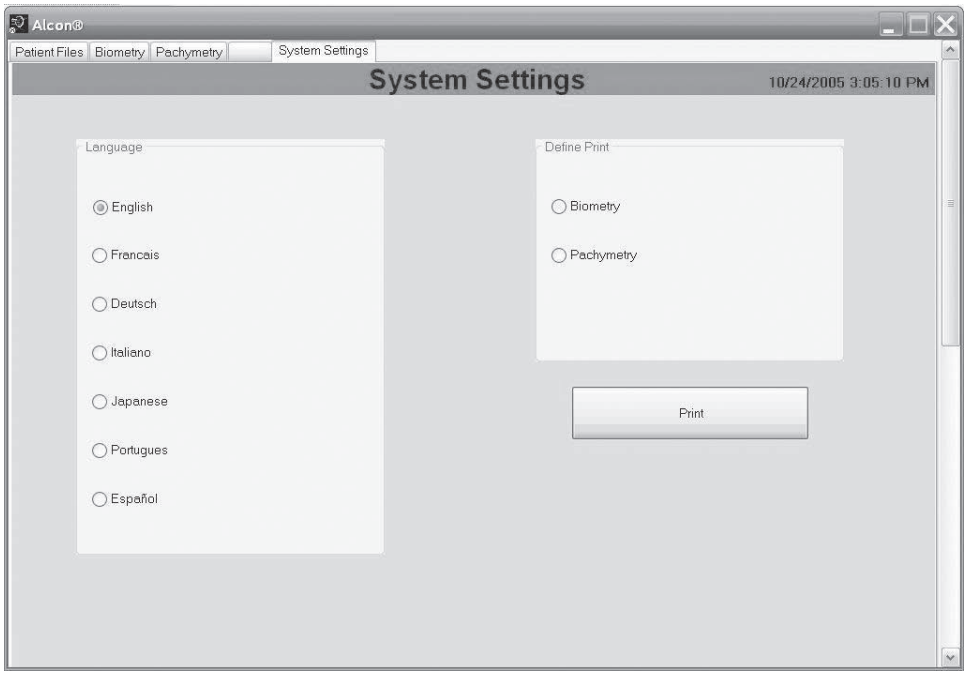


Figure 3-37. SYSTEM SETTINGS IN THE PATIENT VIEWER – This screen shows the systems settings displayed on a PC using the Patient Viewer.

7. Click on the Biometry tab to view the biometry patient data as shown in Figure 3-38.

8. Click on the any of the ten measurements in the display window to display the waveform of that measurement.

9. Zoom in to a specific area of the patient waveform by left-clicking on the waveform and dragging over the area to zoom in on, then release the mouse. To un-zoom, right click on the waveform and select “Undo all Zoom/Pan”.

10. Save an individual waveform to a file for further observation by right clicking on the waveform and select “Save Image As…”.

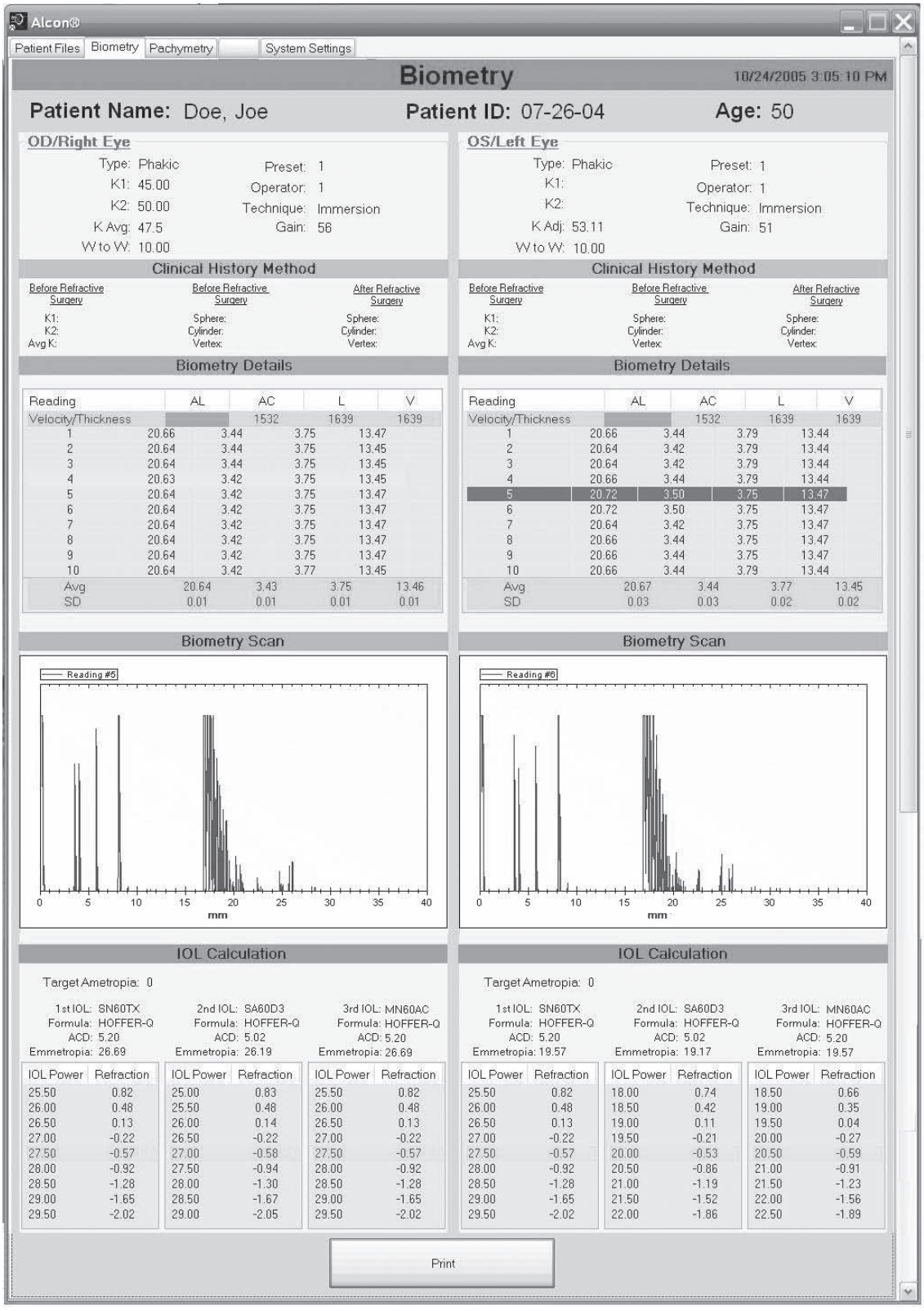


Figure 3-38 BIOMETRY DATA IN THE PATIENT VIEWER – This screen shows the patient's biometry data displayed on a PC using the Patient Viewer.

11. Click on the Pachymetry tab to view the pachymetry patient data as shown in Figure 3-39.

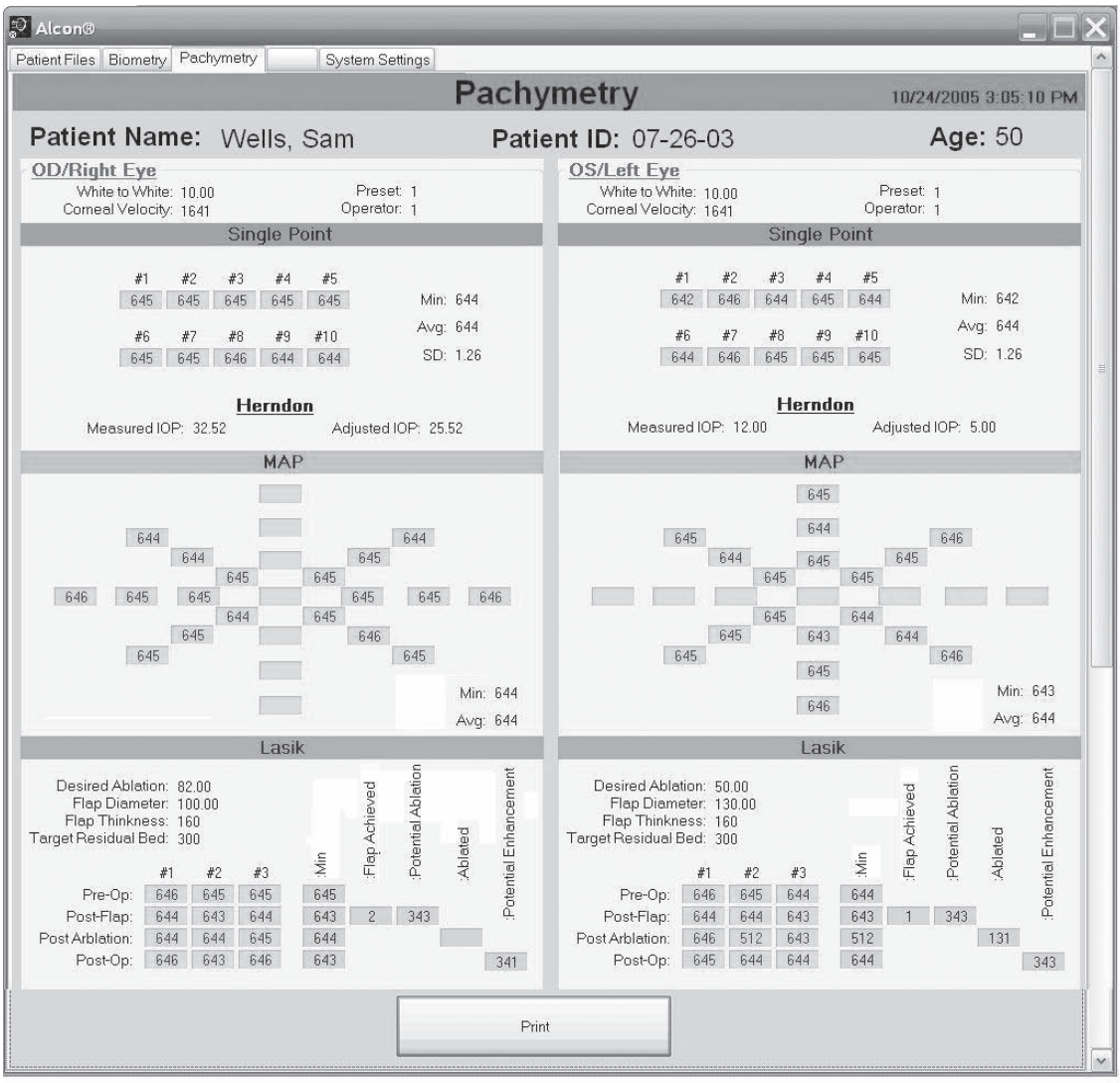


Figure 3-39 PACHYMETRY DATA IN THE PATIENT VIEWER – This screen shows the patient pachymetry data displayed on a PC using the Patient Viewer.

LAST PAGE OF SECTION

SECTION FOUR
CARE AND MAINTENANCE

Maintenance

Operator maintenance/service of the *OcuScan*® RxP Measuring System is limited to that outlined in the OPERATING INSTRUCTIONS and TROUBLESHOOTING sections. A problem that persists following setup and troubleshooting should be referred to your local authorized Alcon service representative.

Alcon's Field Service Representatives are trained and experienced with the *OcuScan*® RxP Measuring System to provide the highest quality of workmanship possible. For warranty information and/or service arrangements, contact your local Alcon representative.

CAUTION

Do not clean console and accessories with solvents or abrasives; irreparable damage will result. Cleaning solutions should be applied to the towel rather than the surface of the console or touch screen to avoid fluid ingress.

Storage

Whenever system is not in service it should be covered with its dust cover. The dust cover protects the console and monitor from airborne particles, and also offers protection against accidental spills.

Cleaning the Console

To clean the console, first turn system power OFF and disconnect the power cord from the power source. The console may be cleaned with a soft, non-abrasive cloth towel and a solution of mild soap and water. Apply the solution to the towel rather than the console.

Cleaning the Touch Screen

The touch screen may be cleaned with a soft, non-abrasive cloth towel and any commercially available window cleaner. Apply the cleaner to the towel rather than the touch screen.

Taking Care of the Biometry and Pachymetry Probes

Follow the guidelines in Table 4-1 to ensure proper care and disinfection of the probes.

WARNING!

Do not use this product on eyes when corneal integrity is compromised by infection or trauma.

CAUTION

The Biometry and Pachymetry probes are fragile components which must not undergo rough use or handling; this can destroy or alter the operation of the probe.

Table 4-1. Decontamination of Biometry and Pachymetry Probes

WARNINGS:	1. Do not use this product when corneal integrity is compromised by infection or trauma. 2. The probes are fragile components which must be handled carefully to ensure proper operation. 3. The probes should be cleaned immediately after use. Do not use abrasive cleaners on the tips. 4. The probes must be thoroughly rinsed after disinfection to protect the eye from residual solution.
Limitations on Reprocessing:	End of life is normally determined by wear and damage due to use.
INSTRUCTIONS	
Point of Use:	Before use: Rinse the probe tip thoroughly with distilled water and dry with a soft clean cloth. After use: Clean and disinfect probe. Replace the probe in its holder, located on the side of the display, with the probe tip pointing up.
Preparation for Decontamination	Disassembly not required.
Cleaning: Automated	Not applicable
Cleaning: Manual	Wipe the entire probe and cable with a cloth moistened with alcohol. Only the tip of the biometry probe up to 15mm from the distal end and the clear, conically shaped tip at the distal end of the pachymetry probe can be immersed.
Disinfection:	To inactivate *Conventional Infectious Agents* such as bacteria and fungi: • Immerse the distal tip of the probe in a 0.5% solution of sodium hypochlorite (5,000 ppm available chlorine, reference the Dilution Guide below) for 5 minutes as follows: o Pachymetry Probe: immerse the clear conically shaped tip at distal end o Biometry Probe: immerse distal end up to 15mm • Immediately after immersion, remove excess hypochlorite solution with a clean cloth, and rinse the probe tip thoroughly with flowing distilled water to ensure residual solution has been removed. Dry with a soft clean cloth. To inactivate Unconventional Infectious Agents, such as prions believed to cause Transmissible Spongiform Encephalopathy (TSE), the World Health Organization (WHO) recommends: • Immerse the distal tip of the probe in a 2% solution of sodium hypochlorite (20,000 ppm available chlorine, reference the Dilution Guide below) for 60 minutes as follows: o Pachymetry Probe: immerse the clear conically shaped tip at distal end o Biometry Probe: immerse distal end up to 15mm • Immediately after immersion, remove excess hypochlorite solution with a clean cloth, rinse the probe tip thoroughly with flowing distilled water to ensure residual solution has been removed. Dry with a soft clean cloth. (Reference: WHO/CDS/CSR/APH/2000.3, "WHO Infection Control Guidelines for TSEs")
Drying:	Use a soft clean cloth to dry probe.
Maintenance, Inspection & Testing:	Inspect probe tip to ensure it is visibly clean and dry.
Packaging:	Not applicable
Sterilization:	Not applicable
Storage:	Whenever the system is not in service it should be covered with its dust cover. The dust cover protects the console and monitor from airborne particles and also offers protection against accidental spills.

ADDITIONAL INFORMATION

Dilution Guide:

Start with a commercial solution of sodium hypochlorite such as: % (ppm) available chlorine	***Combine this amount of sodium hypochlorite solution***	***With this amount of distilled water***	***To obtain 100 ml of sodium hypochlorite solution % (ppm) available chlorine***
5% (50,000 ppm)	40 ml (1/2.5 dilution)	60 ml	2% (20,000 ppm)
5% (50,000 ppm)	10 ml (1/10 dilution)	90 ml	0.5% (5,000 ppm)
2% (20,000 ppm)	Undiluted	n/a	2% (20,000 ppm)
2% (20,000 ppm)	25 ml (1/4 dilution)	75 ml	0.5% (5,000 ppm)
1% (10,000 ppm)	50 ml (1/2 dilution)	50 ml	0.5% (5,000 ppm)

Manufacturer Contact	*By phone:* Contact Technical Services in the USA at 800-832-7827 or contact the local Alcon representative. *By mail:* Alcon (Technical Services) 15800 Alton Parkway Irvine, CA 92618 USA Note: Each probe is identified by a serial number which should be given to the Alcon representative when discussing the probe. This provides traceability.

Installing Paper into the Printer

NOTE: When the paper nears the end of the roll, a red stripe will appear on one edge. When the red stripe appears, tear off the paper then press Reverse in the System Setup screen to back the paper out of the printer. Install a new roll as described in the following steps.

1. From the Menu screen tap System Setup. On the right side of the screen there are three buttons that control the printer paper movement: Load, Forward, and Reverse.

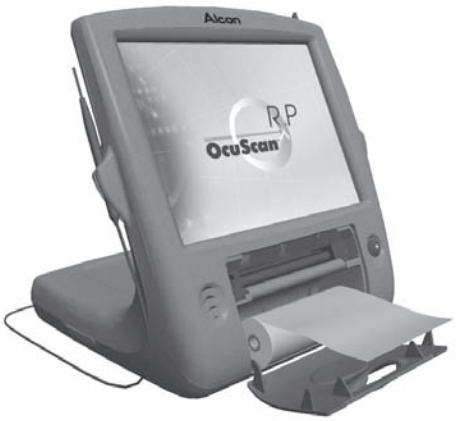
2. Ensure that the paper has a straight cut before loading. A straight edge perpendicular to the outside edge of the roll is critical to proper loading.

3. Open the printer door located on the front of the console and insert the roll of paper in the orientation shown in Figure 4-1.

4. Insert the paper into the opening under the black roller.

5. Press the Load button. The paper will automatically load and should run smooth and straight through the black roller. If not, press reverse to remove the paper, then attempt to load again.

6. Press the Load button again and tear off the excess paper.



Place paper roll into the system in the position shown above.

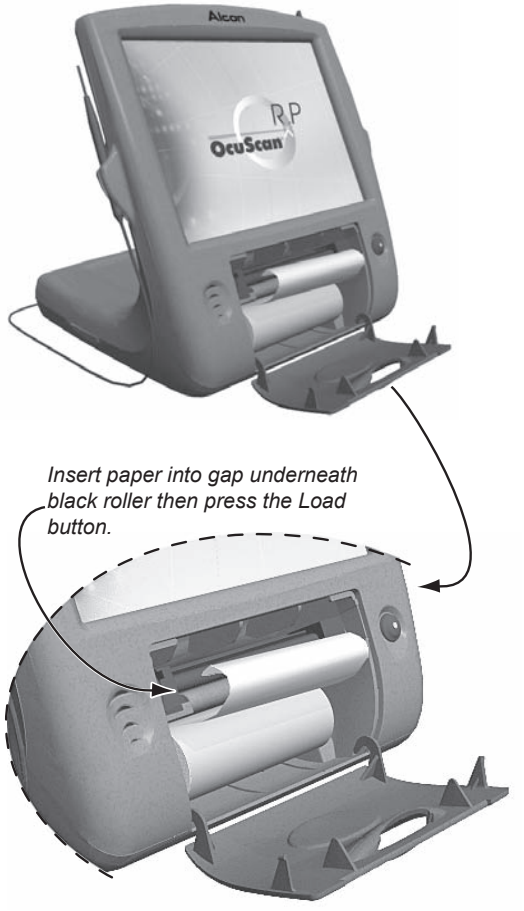


Figure 4-1 PRINTER PAPER INSTALLATION - This illustration shows the proper orientation for installing the printer paper.

LAST PAGE OF SECTION

SECTION FIVE
TROUBLESHOOTING

OcuScan® RxP Troubleshooting Instructions

This section of the manual is designed to help identify and correct problems that may occur with the system. Table 5-1 contains three columns of information. The first column labeled Condition Or Error Message lists the observed problem. The Possible Cause column lists the possible reasons for the observed problem. The last column, labeled Correction, suggests how to correct the problem.

If, after performing the recommended corrective action, the system continues to malfunction, contact your local Alcon service representative.

CONDITION OR ERROR MESSAGE	POSSIBLE CAUSE	CORRECTION
System does not turn ON and front panel LED does not illuminate when power switch actuated.	Power not reaching *OcuScan*® RxP system.	1. Check that power cord is properly connected to power source (wall outlet) and the console rear panel. 2. Check that the Power-on switch on the power supply is ON.
Screen is blank and LED is OFF.	System is in standby state.	Press the Standby button.
When print is initiated, system advances paper but there is no printout.	Improper orientation of the printer paper.	Load the paper with the proper orientation as shown in Figure 4-1.
Scans contain a lot of noise or strange waveforms.	Probe connector not seated properly in the rear panel connector.	Ensure probe is properly connected to rear panel.
No A-scan when system is in running mode and probe is placed on eye model or eye.	Improper connection or system configuration.	1. Confirm that the Biometry probe is properly plugged into the rear panel connector. 2. If probe is being placed on the eye model then make sure that the tip of the probe was dipped in water. 3. Check system configuration; Eye type selection, Technique, Mode, Gain. Use Contact technique for eye model (at the back of the system) and low Gain.
Cannot get measurements in Auto Mode.	Scan peaks do not meet software criteria. Continued on next page...	1. Confirm the probe alignment with the eye (must be perpendicular) and all peaks have sufficient amplitude. 2. If some peaks do not have sufficient amplitude then use Forced Freeze Capture or Manual mode.

Table 5-1. TROUBLESHOOTING CHART - This table contains three columns of information. The first column labeled Condition or Error Message lists the problem or error message observed. The Possible Cause column lists the possible reasons for the problem observed. The last column, labeled Correction, suggests what you can do to correct the problem.

CONDITION OR ERROR MESSAGE	POSSIBLE CAUSE	CORRECTION
Cannot obtain measurements in Immersion mode.	Improper position of probe.	1 Make sure probe tip is 1.5 to 9.8 mm from cornea. 2. Align probe to be perpendicular so cornea peaks are clearly displayed and retina peak is going straight up before releasing the footswitch.
Not able to calculate IOL power.	Necessary data not entered into system.	Confirm that Axial Length data and K values have been entered for the eye.
Improper footswitch function in Manual or Auto mode.	Improper connection.	Check that the footswitch connector is properly plugged into the back panel.
The system goes through unnecessary screens while sequencing via Next arrow key.	Settings screen is not configured.	Configure the Sequence of screens that you normally use in the Settings screen.
Not able to reposition the gates.	System not in Gate Edit mode or improper technique in moving gates.	In frozen mode touch the screen enter Gate Edit mode and tap on Gate Select key until the desired gate is selected.
In Pachymetry, the system does not take measurements.	Pachymetry probe not properly connected.	Insert the Pachymetry probe connector.
Pachymetry measurement in Map or Single point is incorrect.	Incorrect Bias selection.	Select proper Bias for either % or absolute Bias. The Actual selection will display the actual reading with no bias applied.
System not responding or displays error messages.	System failure.	Power system down, then power back up. On systems 685-0000-502 and above (see REF number on label), press and hold the standby switch for 7 seconds then release to reset (reboot) the system. If problem persists, do not use the system. Contact your local Alcon representative.

Table 5-1. TROUBLESHOOTING CHART (continued from previous page)

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SECTION SIX
ACCESSORIES AND PARTS

Following is a list of Alcon-approved accessories and replacement parts for the *OcuScan*® RxP Measuring System. Use of non-approved accessories is not recommended.

For more information, or for an updated list, please contact your local Alcon representative or:

Phone:
(800) 862-5266 or (817) 293-0450
ask for Customer Service

Write:
Alcon, Inc.
6201 South Freeway
Fort Worth, TX 73134-2099

ITEM	CATALOG NUMBER
OcuScan® RxP Measuring System	8065741076

OcuScan*® *RxP Accessories *(included with system)*

Footswitch Assembly	8065741075
Stylus	8065750130
Printer Paper	8065750128
Operators Manual	8065750127
Power Supply	8065750728
Dust Cover	8065750213
USB Driver/Patient Viewer CD	8065750398

OcuScan*® *RxP Optional Items

Angled Pachymetry Probe	8065750122
Straight Pachymetry Probe	8065741077
Biometry Probe with Applicator	8065741073
Biometry Probe without Applicator	8065750123
Compact Flash with Pachymetry	8065750222
Compact Flash, Patient Records	8065750125
Compact Flash with Haigis Formula	8065750124
Power Cord (United States and Canada only)	ULTRAB-054
Service Manual	8065750242

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SECTION SEVEN
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